FOURTH QUARTER & FULL YEAR 2025 EARNINGS PREPARED REMARKS

Dan Maller, VP, Head of Investor Relations

Hello and welcome. Thanks for joining us today. I'm Dan Maller, Head of Investor Relations at BeOne Medicines.

Before we begin, please note that you can find additional materials, including a replay of today's webcast and presentation on the Investor Relations section of our website, ir.beonemedicines.com**.**

[CLICK to SLIDE 2]

I would like to remind all participants that during this call we may make forward-looking statements regarding, among other things, the company's future prospects and business strategy.

Actual results may differ materially from those indicated in the forward-looking statements as a result of various factors, including those risks discussed in our most recent periodic report filed with the SEC. Please also carefully review the forward-looking statements disclaimer in the slide deck that accompanies this presentation.

Reconciliations between GAAP and non-GAAP financial measures discussed on this call are provided in the appendix to our presentation, which is posted to our investor relations website along with our earnings release.

All information in this presentation is as of the date of this presentation, and we undertake no duty to update such information, unless required by law.

[CLICK to SLIDE 3]

Now turning to today's call, as outlined on slide 3, John Oyler, our Co-Founder, Chairman and CEO will provide a business update, including commentary on our foundational CLL franchise; Aaron Rosenberg, our CFO, will provide an update on our fourth quarter financial results and 2026 financial guidance, and Lai Wang, President and Global Head of R&D, will discuss our R&D and Pipeline Progress.

We will then open the call to questions. Joining the team for the Q&A portion of the call will be Xiaobin Wu, President and Chief Operating Officer, Matt Shaulis, General Manager of North America, Mark Lanasa, Chief Medical Officer for Solid Tumors, and Amit Agarwal, Chief Medical Officer for Hematology.

I'll now pass the call over to John.

John?

John V. Oyler, Co-Founder, Chairman and CEO

[CLICK to SLIDE 4]

Thanks Dan, and thank you everyone for joining us today.

[CLICK to SLIDE 5]

Q4 marked another solid quarter of execution and a strong finish to the year. And what a year it was. 2025 certainly lived up to its promise as a year of inflection for BeOne.

From a financial perspective, we delivered on our commitments, achieving significant product revenue growth, GAAP profitability, and meaningful cash flow generation.

[CLICK to SLIDE 6]

In 2025, our foundational BTK inhibitor, BRUKINSA, became number one, both in the U.S. and globally. As you can see on this slide, the gap between BRUKINSA and the competition is widening.

That's not just a commercial achievement—it's a scientific one.

BRUKINSA's long-term data have consistently raised the bar in CLL, setting a new standard for efficacy and safety. These results are reinforced by an expanding body of clinical and real-world evidence, all of which support the program's best-in-class hypothesis.

CLL is a 12 billion dollar and growing market due to remarkable therapeutic innovation and improvement in patient outcomes over the past 15 years.

But it wasn't always that way.

[CLICK to SLIDE 7]

As recently as the mid-2000's, patients with CLL received fixed-duration chemo…and outcomes were poor. In fact, the median progression-free survival for patients taking chlorambucil was less than one year.

In 2008, bendamustine was approved and its use in combination with rituximab became widespread, providing substantial benefit over the first chemo-based regimens. Six-year progression-free survival increased to 32%. Better, but still not great.

The FDA approval of ibrutinib in 2016 marked the first chemo-free option and a seminal innovation for patients. Anchored by data that were superior to chemo, the field switched away from fixed-duration approaches to continuous BTK inhibition, because it provided the best long-term outcomes for patients. You can see ibrutinib's 6-year progression-free survival and overall survival of approximately 61% and 77%, respectively.

At the same time, the field was developing new fixed-duration treatments that were enabled by the discovery of BCL2 inhibition and the approval of venetoclax. These ven-based approaches greatly improved upon historic, chemo-based regimens, and began to approach the long-term benefits provided by the first two continuous BTKis – albeit with an approximately 10% delta in 6-year progression-free survival. However, the VI regimen was not approved by the FDA and the addition of obinutuzumab to ven has significant safety challenges, which I'll touch on later.

As good as continuous use ibrutinib was, the molecule was not optimized for potency or selectivity. The second approved BTK inhibitor, acalabrutinib, was designed to be more selective than ibrutinib and to have a very short half-life of roughly one hour – with the hypothesis that these changes would translate to a more favorable safety profile, including fewer cardiac adverse events.

In that respect, acala achieved its goal, demonstrating a statistically significant improvement in afib in the Elevate R/R study. However, in that same study, acala demonstrated non-inferior PFS compared to ibrutinib.

As shown on this scatterplot, acala's 6-year progression-free survival and overall survival of 62% and 76% in treatment-naïve CLL is nearly superimposable on ibrutinib.

But innovation never stops. The bar set by the first two continuous treatments would be raised yet again, by a differentiated, foundational medicine.

Enter BRUKINSA.

BRUKINSA was designed from inception to be both more potent AND more selective than ibrutinib, with complete 24/7 target coverage. We took that preclinical hypothesis to the clinic where, in a head-to-head, global Phase 3 trial, BRUKINSA demonstrated superior efficacy to ibrutinib AND a more favorable safety profile, including a statistically significant improvement in afib.

And at ASH 2025, BRUKINSA set a new bar for long-term patient outcomes.

Here we see 6-year progression-free survival and overall survival of 74% and 84%. Adjusting for COVID, those are 77% and 87%, respectively.

With these data, BRUKINSA has clearly established the foundational standard against which all current and future regimens must be compared and the long-term outcomes that patients and physicians should expect and demand.

[CLICK to SLIDE 8]

At BeOne, we believe that true innovation comes from improving upon the best.

BRUKINSA did just that when it demonstrated superiority in terms of safety and efficacy over ibrutinib. No other BTK inhibitor can make that claim.

Here we see the Kaplan Meier curves from head-to-head trials of BRUKINSA and other BTK inhibitors versus ibrutinib, in relapsed or refractory BTK-naïve CLL patients, as assessed by Independent Review Committee, or IRC. In all of these studies, IRC-assessed PFS is the predefined key secondary endpoint to demonstrate superiority over ibrutinib.

In the ALPINE trial, BRUKINSA showed the greatest early separation from ibrutinib and remains separated, with a hazard ratio of .69 and a p-value of .001 demonstrating statistical superiority on PFS. We presented longer-term follow-up data from that study at ASH last year.

In the Elevate RR study, acala showed early PFS separation from ibrutinib, albeit less than BRUKINSA, but that early separation was not sustained. As you can see in the middle chart, acala crossed over and became numerically worse than ibrutinib at roughly 33 months. ELEVATE-RR ultimately reported a hazard ratio of 1.

This brings me to pirtobrutinib, a non-covalent BTK inhibitor, which recently reported data from its head-to-head trial against ibrutinib in CLL.

On the right, we see the curves from the relapsed refractory BTKi naïve cohort of BRUIN-314, which comprised two thirds of enrolled patients in that trial.

You can see that pirto, with only 18 months of follow up, shows the least early separation versus ibrutinib, with a hazard ratio of .845 and a p-value of .4102.

We need to see much longer follow-up from BRUIN 314 but based on the minimal early separation in these short-term curves, pirto may face an uphill battle in showing statistical superiority to ibrutinib on PFS.

[CLICK to SLIDE 9]

If you've learned anything about BeOne Medicines over our 15 years of existence, it's that we're never satisfied with the status quo.

Despite the incredible progress the industry has made, it's hard not to dream about the next chapter in CLL innovation.

We think it's time to start talking about a cure.

And with that, we propose three aspirational goals for the next wave of innovation in CLL:

The first is an obvious one – life expectancy equal to that of the general population – matched for geography and age – for any patient diagnosed with CLL.

Second, for patients who prefer a time-limited therapy, any regimen must deliver long-term outcomes at least as good as the best continuous treatment available.

And finally, any treatment designed to offer long-term life expectancy must also deliver quality of life, ease of use, and convenience.

Applying these aspirations to the scatter plot implies the need for further improvements on what is currently available.

We believe BeOne is the only company with the foundational assets in our CLL portfolio and pipeline to take us there.

[CLICK to SLIDE 10]

The next chapter of CLL innovation will come from options that address unmet needs and deliver the best long-term outcomes for patients.

So, what about fixed duration?

There is a clear desire from some patients and physicians for fixed duration options that provide a break from treatment. For fixed duration to change the treatment paradigm, it must elicit a deep response, demonstrate sustained progression-free survival, be safe with only minimal infection risk over continuous BTKi, and be convenient to administer.

And, we would argue, it must be compared to the foundational CLL medicine, BRUKINSA.

Naturally, patients want to be off treatment, but just as they want to know what they are gaining, every patient wants to know what they are giving up. If that's overall survival, it's important that this is considered in the shared decision-making.

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So how do the current fixed-duration options compare to BRUKINSA?

In our opinion, not very well.

Existing ven-based-BTKi regimens have liabilities that have limited their uptake and approval.

These include underwhelming efficacy as seen in the AMPLIFY trial, where the AV combination had an inferior depth of response compared to chemo, demonstrating uMRD of only 34%, despite AMPLIFY enrolling a young, fit, and low-risk front-line population. In fact, AV's PFS at three years follow up was roughly the same as BRUKINSA's at six years. It's noteworthy that we haven't seen an updated data cut from AMPLIFY for nearly 2 years.

And similarly with respect to safety, AV and VI have limitations due to ven, a less potent and less selective first generation BCL2 inhibitor.

In terms of convenience, the low depth of response for AV may result in most patients having to be treated for far longer than one year to reach undetectable MRD. In addition, ven requires cumbersome patient monitoring due to its long half-life and TLS risk, which calls into question the convenience benefit of this all-oral regimen.

[CLICK to SLIDE 12]

At the highest level, the primary benefit of fixed duration therapy is the treatment-free interval, during which patients are not exposed to the potential side effects of ongoing therapy. In CLL, this means avoiding agents that suppress rapid B-cell expansion, allowing for immune recovery and a reduced risk of infection.

So, fixed duration therapies should lower infection risk over time—not raise it.

The CLL17 trial studied fixed duration VO and VI versus continuous ibrutinib and was presented at ASH last year. The chart on the left shows the CLL17 trial data, which tells a clear – and quite concerning - story.

First, after one year of VO, severe infections continued to climb for the three years while the patient was off treatment, as seen in blue. These infections are serious, often requiring hospitalization and IV antibiotics.

Second, even after four years, severe infections were still higher with VO than with continuous ibrutinib despite a three-year treatment-free period.

As a reminder, BRUKINSA demonstrated roughly one third fewer grade 3/4 infections versus ibrutinib in the ALPINE study.

The VO arm also showed a 67% nominally increased risk of death versus ibrutinib.

These findings are quite consistent with data from other recent studies, such as AMPLIFY, where the AVO regimen was not FDA-approved. In fact, the FDA specifically called out the higher death rate due to infections from the AVO arm.

In our view this profile stands in direct opposition to what patients want and deserve from a fixed duration treatment.

And if you now look at the table on the right, for the highest risk patients—roughly half of all CLL patients—VO shows notably lower PFS. This data shows that patients have an approximately 50% higher chance of progressing within 6 years.

50%.

There is a narrative that the current fixed duration options are good.

If someone I love was diagnosed with CLL, my first inclination might also be toward fixed duration. But, if I knew that the disease had a potentially 50% higher chance of progressing within six years. And if I knew that fixed duration wasn’t reducing the risk of serious infection over 4 years, just accelerating it into the earlier years, I would encourage them to think twice.

The risk benefit profile of current fixed duration regimens simply does not justify a shift away from established continuous BTKi therapy.

[CLICK to SLIDE 13]

The evidence that existing time-limited therapies may not provide long-term outcomes comparable with BRUKINSA continues to build.

Here, we can see three recently published matched adjusted indirect comparisons of BRUKINSA vs. AV, VI and VO which reach that conclusion. And these reflect the early trends we are seeing in real-world data.

[CLICK to SLIDE 14]

Our goal for patients that prefer a fixed duration treatment option is simple.

We aim to develop a more efficacious, time-limited regimen that does not come with caveats or accommodations.

And we believe ZS is that therapy.

The clinical data being generated by combining a best-in-class BTK inhibitor with a potentially best-in-class BCL2 inhibitor just looks different.

With all the caveats of cross trial comparison, ZS has demonstrated the highest uMRD rate and highest PFS for the respective follow-up when compared to other venetoclax-based fixed duration therapies. ZS shows a favorable safety profile, with fewer high-grade adverse events and no deaths.

In terms of patient convenience, we have not yet observed any clinical or laboratory TLS, and we are very optimistic that for most patients, only one clinic visit during ramp-up will be required after zanu lead-in.

[CLICK to SLIDE 15]

Today, the CLL landscape is roughly split evenly into patients who receive continuous BTK inhibitors and those who receive some form of fixed duration treatment.

Currently, BRUKINSA captures approximately half of the continuous BTK segment of the market.

ZS will enable BeOne to participate in the other half of the market where today we have no presence.

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In summary, BeOne remains the only company with fully owned, potentially best-in-class assets across three foundational MOAs in CLL: BRUKINSA. Sonro. And our BTK CDAC.

As I said earlier, we think it’s time to start talking about a cure.

All three of these foundational assets, whether as monotherapy or in combination – represent the next chapter in CLL innovation, raising the bar for patients everywhere.

Now I’ll pass it over to Aaron to provide the Financial Update.

[CLICK to SLIDE 17]

Aaron Rosenberg, Chief Financial Officer

Thanks, John.

[CLICK to SLIDE 18]

I am pleased to share our fourth quarter and full year results where we delivered against all of the financial commitments that we established in the beginning of 2025.

Product revenue reached $1.5 billion in the fourth quarter, representing 32% year-over-year growth.

BRUKINSA global revenues totaled $1.1 billion, growing 38% with strong performance across all geographies. For full year 2025, BRUKINSA global revenues were $3.9 billion, representing growth of 49%. As John shared earlier, BRUKINSA has established itself as the leading BTKi globally by an increasing margin, as we closed 2025.

In the US, BRUKINSA fourth quarter sales were $845 million driven by volume growth of approximately 30% versus Q4 2024.

Our leadership is directly linked to the differentiated breadth, quality and consistency of BRUKINSA's clinical data, including those shared at ASH 2025. Pricing dynamics in the United States were consistent with commentary provided last quarter, with a mid-single digit pricing benefit on a year-over-year basis.

These results include the previously mentioned, typical, seasonality benefits seen in the final quarter of the year for both current year performance and the 2024 baseline.

Meanwhile, TEVIMBRA reported an 18% increase, reflecting continued market leadership in China. This growth was supplemented by contributions from launch markets.

Our in-licensed products also showed continued strength, growing 9% year-over-year.

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We continue to observe solid execution across geographies. The U.S. remains our largest market, generating $850 million with year-over-year growth of 38%.

China revenue totaled $399 million, an 11% increase compared to the fourth quarter of 2024, supported by TEVIMBRA and BRUKINSA's market leadership, and growth from our in-licensed assets.

Europe contributed $174 million, with 53% year-over-year growth as we continue our launch trajectory with BRUKINSA with increased share across all major markets.

And Rest of World markets grew 74% driven by market expansions and new launches.

[CLICK to SLIDE 20]

Now turning to the other components of our GAAP P&L and my commentary will be on a full year basis unless otherwise noted.

Gross margin improved to 87% from approximately 84% in the prior year. This year-over-year improvement primarily reflects the benefits from favorable product mix, price, and product cost efficiencies.

Operating expenses grew by 12%, totaling $4.2 billion as we are investing with discipline to support our commercial growth and rapidly advance our innovative pipeline.

Income from operations totaled $447 million, showcasing the inflection in 2025 to a company that is at scale and profitable.

Bridging from operating to net income, “other income and expense” included a non-recurring $40 million equity investment impairment in the fourth quarter.

Income tax expense totaled $130 million for 2025 increasing from $112 million in 2024, including $25M of non-recurring tax expenses and $20M of timing related tax expenses in certain geographies. These effects, in part driven by our valuation allowance status, disproportionally impacted the fourth quarter.

Altogether, and including these one-time items, net income reached $287 million with GAAP diluted earnings per ADS of $2.53.

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Our non-GAAP P&L includes adjustments for typical items with a full reconciliation provided in the appendix.

Non-GAAP income from operations totaled $1.1 billion in fiscal 2025, up from $45 million in 2024.

And non-GAAP net income came in at $918 million for full year 2025, which translates to diluted non-GAAP earnings per ADS of $8.09 for 2025.

We continued our strong trend of cash flow generation, with free cash flow of $380 million in Q4. Full year 2025 free cash flow was over $940 million.

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Now, turning to our 2026 financial guidance.

We expect another strong year of revenue growth with continued global leadership for BRUKINSA. We anticipate that the U.S. will continue to see strong demand growth, and with relatively stable net pricing.

Growth is anticipated in all markets and will benefit from continued global expansion in important Rest of World markets.

We anticipate modest initial contributions from our launches of sonrotoclax and zanidatamab as physicians begin to gain experience with these medicines ahead of launches in their respective larger market opportunities. We are pleased that these practice-changing medicines are becoming available to patients as they fulfill important unmet medical needs.

In total, we project 2026 revenue to be between $6.2 billion to $6.4 billion.

As you model quarterly phasing for 2026, please recall that we expect similar seasonality and shipping weeks in Q1 2026 as we observed in Q1 2025, and therefore we believe it is more useful to consider year-over-year growth rates in this upcoming period.

Our GAAP gross margin percentage is expected to be in the high-80% range with continued benefit from mix and a full year of productivity from improvements implemented last year.

Operating expenses on a GAAP basis are anticipated to be between $4.7 billion and $4.9 billion. This level of investment ensures we are positioned to capture the full value of our commercial and late-stage pipeline opportunities.

GAAP operating income is expected to be between $700 and $800 million and non-GAAP operating income is expected to be between $1.4 and $1.5 billion.

In terms of other income and expense, we expect expenses to be between $25 to $50 million. This includes interest expense associated with the Royalty Pharma arrangement.

Turning to income taxes. We have historically been in a valuation allowance whereby our accumulated deferred tax assets have a reserve against them.

Given our recent history of earnings, we believe there may be sufficient positive evidence to recognize a portion of these assets in 2026. The exact timing and magnitude are uncertain, but we believe that a potential reversal would result in a material tax benefit to the income tax provision when recognized.

When this reversal fully occurs, we will reflect deferred taxes in our financial statements, and our effective tax rate will become a more meaningful and predictable metric. We will provide additional updates on income taxes throughout the year.

In summary, we are pleased with our performance in 2025 and like our setup for continued growth and financial strengthening as reflected in our 2026 guidance.

I would be remiss if I did not take this opportunity to thank our global teams across all parts of BeOne for their incredible dedication to our company’s purpose, and the corresponding results that can be seen so clearly in our financial performance.

And with that, I’d like to pass the call over to Lai.

Lai Wang, President, Global Head of R&D

[CLICK to SLIDE 23]

Thank you, Aaron

Hi everyone, thanks for joining us today.

[CLICK to SLIDE 24]

2025 has been a standout year for BeOne R&D.

Most notably, it was a breakout year for sonro. We achieved our first global approvals in China for relapsed/refractory MCL and CLL. In addition, regulatory submissions for relapsed refractory MCL are under review in both the U.S. and EU, with FDA approval expected in the first half of this year.

Our BTK degrader continues to advance steadily toward registration. In 2025, we initiated three Phase 3 studies, including a head-to-head trial versus pirto.

In solid tumors, we also made strong progress. TEVIMBRA delivered a positive Phase 3 readout in HER2 positive gastric cancer in combination with zanidatamab and chemotherapy.

Importantly, the next wave of innovation is here. In 2025 alone, five new assets achieved clinical PoC, and over the past two years, we have advanced 17 new molecular entities into the clinic.

[CLICK to SLIDE 25]

BeOne has moved through two defining chapters in our history.

In the first ten years, we built from the ground up. With limited capabilities, we delivered two breakthrough medicines—BRUKINSA and TEVIMBRA—and proved that BeOne could innovate at the highest level.

The second chapter, over the past five years, was about scale and readiness. We invested heavily to build a powerful discovery engine and a truly differentiated global clinical development superhighway—transforming BeOne from a company with isolated wins into one capable of repeatable success.

Today, we are positioned better than ever to deliver a continuous stream of innovation.

2026 marks the beginning of a new era for BeOne.

Over the next three years, we are focused on four priorities.

First, we will deepen our leadership in CLL, building on our three foundational medicines.

Second, we will expand across hematologic malignancies, including indolent and aggressive lymphomas as well as AML.

Third, we will establish BeOne as an oncology powerhouse in solid tumors, with leadership in three strategically chosen subtypes, driven by both internal innovation and external partnerships.

And finally, we plan to advance one to two potential cornerstone immunology assets toward registration.

It took us 15 years to build the CLL franchise. We believe we can move faster—and do even better—across other diseases. With greater scale and a sense of urgency, we can reach far more patients than ever before.

[CLICK to SLIDE 26]

In CLL, today BRUKINSA is approved for both treatment-naïve and relapsed/refractory patients, giving us a strong foundation.

Looking ahead, in the frontline setting, BRUKINSA will serve as the foundational therapy—either as continuous treatment or, for patients who prefer finite therapy, as a potentially best-in-class fixed-duration regimen in combination with sonro.

In the relapsed and refractory setting, BeOne will offer BTK CDAC–anchored treatments. We see a potential accelerated approval opportunity for our BTK CDAC as a continuous use monotherapy as early as next year based on the Phase 2 single arm study, with three Phase 3 studies underway to establish strong evidence versus current standard of care.

Beyond that, we believe the BTK CDAC and sonro combination has the potential to deliver best-in-class fixed-duration therapy for relapsed/refractory patients, with strong efficacy, safety, and convenience. A Phase 3 study is being planned.

Finally, we are also developing an alternative fixed-duration option, combining sonro with anti-CD20 therapy, currently being tested head-to-head against venetoclax in a Phase 3 study.

[CLICK to SLIDE 27]

We are also advancing our three foundational hematology assets across non-CLL indications. These molecules have demonstrated strong activity across multiple B-cell malignancies, including mantle cell lymphoma, Waldenström’s macroglobulinemia, follicular lymphoma, and marginal zone lymphoma.

We are particularly excited about the Phase 3 IA for zanu in combination with rituximab in treatment-naïve mantle cell lymphoma, expected in the first half of this year. If successful, this would represent the first chemotherapy-free regimen in this setting.

In addition, we are expanding sonro into multiple myeloma, with plans to initiate a pivotal Phase 3 study in combination with a CD38 antibody and dexamethasone by the end of this year.

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2026 will also be the year we expand beyond BTK and BCL2 MOAs in hematology-oncology.

A new wave of assets is entering the clinic—led by our proprietary, off-the-shelf, iPSC-derived gamma- delta T- cell therapy. With twelve genetic engineering modifications, this program is highly differentiated and designed to overcome many of the limitations of existing off-the-shelf cell therapies. I am very excited about its potential in clinic.

In parallel, we are advancing T-cell engagers and T-cell boosters for B-cell malignancies, particularly aggressive lymphomas, to address challenges such as tumor antigen loss and inadequate or unsustained T-cell activation.

For AML and MDS, we are building a focused portfolio to address the significant unmet medical need. Beyond sonro, this includes a first-in-indication KAT6 inhibitor, supported by strong translational data, and a next-generation Menin inhibitor designed to overcome all known resistance mutations. We also have additional undisclosed preclinical programs underway that will continue to fuel our future pipeline.

In summary, we have built a hematology portfolio defined by durability, differentiation, and depth—positioning BeOne for sustained impact well beyond our current leadership areas.

With that, let me turn to solid tumors.

[CLICK to SLIDE 29]

Our solid tumor pipeline has evolved dramatically over the past two years.

Previously, our focus was largely on immuno-oncology. Over the last two years, we have fundamentally reengineered the portfolio, shifting toward critical oncogenic signaling pathways across breast, gynecologic, lung, and gastrointestinal cancers, using multiple therapeutic modalities.

As you can see on this slide, we now have more than 20 assets across these focused disease areas. Among them, five programs achieved proof of concept in 2025, and I’ll walk you through these key assets now.

[CLICK to SLIDE 30]

First, based on strong emerging efficacy and safety data from Phase 1 expansion cohorts, we plan to initiate a Phase 3 trial in first-line hormone receptor–positive breast cancer in the first half of 2026. The safety profile suggests potential best-in-class hematologic safety, with manageable gastrointestinal toxicity.

The Phase 3 study will compare BGB-43395 against physician's choice of CDK4/6 inhibitor in combination with letrozole, with progression-free survival by central radiology review as the primary endpoint.

[CLICK to SLIDE 31]

Beyond CDK4, we have four additional solid tumor programs advancing rapidly toward registration, all supported by compelling and evolving clinical data.

- B7-H4 ADC: encouraging activity in gynecologic cancers and triple-negative breast cancer. A Phase 3 study is expected to start within one year.
- GPC3–41BB bispecific: The strength of the positive data from this program has been a pleasant surprise, showing very exciting monotherapy signals in PD-1 pretreated HCC patients in its first-in-human study. A pivotal trial will be initiated before year end.
- PRMT5 inhibitor: This asset stands out with potentially best-in-class potency, selectivity, and brain penetration. Based on emerging Phase 1 data, we are accelerating this program into frontline non-small cell lung cancer.
- CEA ADC: We are seeing promising monotherapy activity in heavily pretreated patients and are planning for the pivotal trials.

It's important to note that all four assets have been in the clinic for less than two years, and three for less than 18 months. This is the level of focus, efficiency, and execution we aim to deliver across the portfolio.

Together, these five PoC assets represent a step change in BeOne's solid tumor impact. With multiple modalities, rapid clinical execution, and clear paths to registration, we are no longer building a pipeline—we are building a solid tumor franchise. And this is only the beginning.

[CLICK to SLIDE 32]

To complement our growing portfolio, we have also invested heavily in clinical execution capability. We now call this our global clinical development superhighway—designed to deliver industry leading speed, quality, and reliability.

Let me give you a few examples.

Over the past two years, we have completed around 200 dose-escalation cohorts across multiple first-in-human studies, with a median of just 1.5 months per cohort. The industry norm is roughly three months.

In late-stage development, last year we completed enrollment of CELESTIAL-TNCLL study with around 700 CLL patients, across 20 countries and more than 200 sites, in just 14 months—and as you know, CLL is not an easy indication to enroll.

On the regulatory side, our most recent NDA—sonro's initial filing with the FDA in mantle cell lymphoma—was completed within one month of topline data. Industry standards are typically four to six months.

Finally, we are equipping this superhighway with AI and automation. Today, we can already deliver near real-time data analysis and insights across all early stage clinical trials. Over the next two to three years, we expect AI and automation to unlock even greater gains in speed, quality, and decision making.

This global clinical development super highway is a core competitive advantage for BeOne—and we look forward to sharing continued progress in future updates.

[CLICK to SLIDE 33]

Very quickly on 2026 catalysts—I've touched on most of them already, so let me highlight a few key ones I haven't mentioned yet.

First, we just initiated a global Phase 3 study of ZS versus AV in treatment-naïve CLL, directly comparing two all-oral fixed-duration regimens.

Second, in the first half of this year, we expect to file tislelizumab for HER2-positive gastric cancer, in combination with zanidatamab and chemo.

And finally, in immunology, we anticipate multiple proof-of-concept readouts this year, including BTK CDAC in CSU and IRAK4CDAC in RA.

I will now turn it back to John.

[CLICK to SLIDE 34]

John V. Oyler, Co-Founder, Chairman and CEO

Thanks, Lai.

We will now open the call to Q&A.

Q&A

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