PhaseBio Announces European Licensing Agreement with Alfasigma S.p.A for Commercialization of Bentracimab

June 17, 2021

Agreement provides PhaseBio with $20 million upfront payment and eligibility to receive up to $245 million in development and commercial milestones in addition to tiered double digit royalties on sales

Collaboration reinforces global bentracimab opportunity

Establishes accessibility to bentracimab, if approved, for the largest pool of ticagrelor patients in the world

PhaseBio to host conference call today at 5:30 am PST / 8:30 am EST

MALVERN, Pa., & SAN DIEGO, Calif.--(BUSINESS WIRE)--Jun. 17, 2021-- PhaseBio Pharmaceuticals, Inc. (Nasdaq: PHAS), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary diseases, today announced that it has entered into an exclusive licensing agreement with Alfasigma S.p.A., a privately owned specialty pharmaceutical company focused on commercializing medicines in Europe and other key markets, for the commercialization of bentracimab. The agreement covers countries in the European Union and European Economic Area, as well as the United Kingdom, Russia, Ukraine and other countries within the Commonwealth of Independent States. Bentracimab is a novel, human monoclonal antibody fragment that in earlier clinical trials has shown immediate and sustained reversal of the antiplatelet effects of Brilinta®/Brilique® (ticagrelor).

Under the terms of the license agreement, PhaseBio will receive a $20 million upfront payment and will be eligible to receive up to $35 million in pre-revenue regulatory milestones and up to $190 million in payments contingent upon the achievement of certain sales milestones. PhaseBio will also receive tiered royalties on net sales, with percentages starting in the low double digits and escalating up to the mid-twenties. PhaseBio will be responsible for developing bentracimab and securing approval with the European Medicines Agency (EMA) and the Medicines and Healthcare Products Regulatory Agency (MHRA), after which marketing authorization will be assigned to Alfasigma. Alfasigma will be responsible for securing regulatory approval in other territories not covered by EMA or MHRA approvals, and for obtaining and maintaining regulatory approvals necessary to market and sell the product, including pricing approvals and post-marketing commitments.

“The signing of this commercialization agreement with our new partner, Alfasigma, is a truly momentous occasion for PhaseBio,” said Jonathan P. Mow, Chief Executive Officer of PhaseBio Pharmaceuticals. “Alfasigma brings deep regional expertise in the hospital environment that we believe will help unlock the value of the global bentracimab brand while enabling PhaseBio to invest in the commercial infrastructure necessary to successfully launch the product in the United States. By establishing bentracimab in key markets where a significant proportion of the global ticagrelor patient population resides, Alfasigma will play a critical role in our mission to change the way patients on antiplatelet therapy are managed. We are excited to have found a collaborator who shares our enthusiasm for the potential of bentracimab to address critical unmet needs and look forward to a long and mutually-beneficial relationship.”

“This agreement marks another important milestone in our journey to establish Alfasigma as a major international specialty company, and a partner of choice for companies seeking to leverage our expertise in key markets across Europe,” said Pier Vincenzo Colli, Chief Executive Officer of Alfasigma. “The unmet need for bentracimab is clear: we are proud to serve these patients and bring this valuable medicine into the Alfasigma family of specialty products. As one of the leading European-based specialty pharmaceutical companies with a hospital presence and a core focus in the vascular therapeutic area and other cardio-metabolic diseases, Alfasigma is well positioned to commercialize bentracimab. We share a high degree of enthusiasm with PhaseBio as we look forward to building the global bentracimab brand across Europe and other key markets.”

Bentracimab is currently in late-stage clinical development in the REVERSE-IT (Rapid and SustainEd ReVERSal of TicagrElor – Intervention Trial) trial. REVERSE-IT is a Phase 3, multi-center, open-label, prospective single-arm trial designed to study reversal of the antiplatelet effects of ticagrelor with bentracimab in patients who present with uncontrolled major or life-threatening bleeding or who require urgent surgery or an invasive procedure. The Company expects to complete enrollment of the first 100 patients in the REVERSE-IT trial in mid-2021 and is targeting to submit its Biologics License Application (BLA) for bentracimab in mid-2022, although those timelines could be impacted by the continued scope and duration of the COVID-19 pandemic. To date, nearly all of the patients enrolled have required urgent surgery or an invasive procedure.

Previously, bentracimab has been studied in Phase 1 and Phase 2 clinical trials and has demonstrated the potential to bring life-saving therapeutic benefit through immediate and sustained reversal of the antiplatelet activity of ticagrelor, potentially mitigating concerns regarding bleeding risks associated with the use of this antiplatelet drug. Additionally, in a translational study, bentracimab achieved equivalent reversal of branded ticagrelor and multiple ticagrelor generics.

Conference Call and Details

PhaseBio leadership will host a conference call today, June 17, 2021, at 5:30 am PST / 8:30 am EST to discuss today’s announcement. To access the call, please dial 866-221-1776 (domestic) or 270-215-9926 (international) and provide the Conference ID 9369434 to the operator.

To access the audio webcast and subsequent archived recording of this presentation, click here or visit the investor section of the PhaseBio website. The archived call will remain available for replay on PhaseBio’s website for 90 days.

About Bentracimab (PB2452)

Bentracimab is a novel, recombinant, human monoclonal antibody antigen-binding fragment designed to reverse the antiplatelet activity of ticagrelor in major bleeding and urgent surgery situations. In a Phase 1 clinical trial, bentracimab demonstrated the potential to bring life-saving therapeutic benefit through immediate and sustained reversal of ticagrelor’s antiplatelet activity, mitigating concerns regarding bleeding risks associated with the use of this antiplatelet drug. The Phase 1 clinical trial of

bentracimab in healthy volunteers was published in the *New England Journal of Medicine* in March 2019. In April 2019, bentracimab received Breakthrough Therapy Designation from the Food and Drug Administration (FDA). Breakthrough Therapy Designation may be granted by the FDA when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapy. In September 2019, PhaseBio completed a Phase 2a trial in which bentracimab was investigated in older and elderly subjects on dual antiplatelet therapy of ticagrelor and low-dose aspirin. Additionally, the Phase 2a trial investigated a bentracimab regimen for the reversal of supratherapeutic doses of ticagrelor in healthy younger subjects. In both arms of the trial, bentracimab achieved immediate and sustained reversal of the antiplatelet effects of ticagrelor and was generally well-tolerated, with only minor adverse events reported. These results are consistent with the results observed in healthy younger subjects treated with ticagrelor in the previously published Phase 1 trial. PhaseBio initiated the REVERSE-IT trial, a pivotal Phase 3 clinical trial of bentracimab, in March 2020 to support a Biologics License Application for bentracimab in both major bleeding and urgent surgery indications. There are currently no approved reversal agents for ticagrelor or any other antiplatelet drugs.

About PhaseBio

PhaseBio Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiovascular and cardiopulmonary diseases. The company's pipeline includes: bentracimab (PB2452), a novel reversal agent for the antiplatelet therapy ticagrelor; pemziviptadil (PB1046), a once-weekly VIP receptor agonist for the treatment of pulmonary arterial hypertension; and PB6440, an oral agent for the treatment of resistant hypertension. PhaseBio's proprietary elastin-like polypeptide technology platform enables the development of therapies with potential for less-frequent dosing and improved pharmacokinetics, including pemziviptadil, and drives both internal and partnership drug-development opportunities.

PhaseBio is located in Malvern, PA, and San Diego, CA. For more information, please visit www.phasebio.com, and follow us on Twitter @PhaseBio and LinkedIn.

About Alfasigma

Privately owned, Alfasigma is an Italy based multinational pharmaceutical company, present in over 90 countries, through distributors and subsidiaries. The company employs a workforce of around 3,000 people, has in-house R&D capabilities, and several production plants. Alfasigma is known for its strong focus on Gastroenterology and Vascular.

More information is available at the corporate website https://www.alfasigma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "believes," "expects," "intends," "projects," and "future" or similar expressions are intended to identify forward-looking statements.

Forward-looking statements include statements concerning or implying the conduct or timing of our clinical trials and our research, development and regulatory plans for our product candidates, the potential for these product candidates to receive regulatory approval from the FDA or equivalent foreign regulatory agencies, and whether, if approved, these product candidates will be successfully distributed and marketed, including through our partnership with Alfasigma. Forward-looking statements are based on management's current expectations and are subject to various risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such forward-looking statements. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements.

Risks regarding our business are described in detail in our Securities and Exchange Commission ("SEC") filings, including in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2021. These forward-looking statements speak only as of the date hereof, and PhaseBio Pharmaceuticals, Inc. disclaims any obligation to update these statements except as may be required by law.

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