August 2, 2021

CymaBay Announces $100 Million Non-Dilutive Financing with Abingworth

Risk-sharing agreement with Abingworth will fund seladelpar Phase 3 development program for PBC

CymaBay retains full worldwide commercial rights to seladelpar

NEWARK, Calif., Aug. 02, 2021 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ: CBAY), a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet need, today announced a $100 million non-dilutive financing transaction with Abingworth to fund the Phase 3 development program for seladelpar in primary biliary cholangitis (PBC), including the Phase 3 RESPONSE clinical trial.

“CymaBay continues to seek the most capital efficient way to fund its pipeline with today’s announcement of a strategic funding arrangement with Abingworth to support the completion of the Phase 3 development program for seladelpar in PBC,” said Sujal Shah, Chief Executive Officer of CymaBay. “By thoughtfully risk-sharing development costs with Abingworth, who shares our belief in the potential of seladelpar to serve as an improved second-line treatment for patients with PBC, we have secured the additional funding needed for the Phase 3 program.” Shah continued, “This transaction provides us with capital needed to complete Phase 3 development and an investor with a long track record of successfully funding innovative companies focused in life sciences.”

Under the terms of the transaction, CymaBay will receive up to $100 million of seladelpar development costs, of which $75 million will be received in three installments over approximately six months. CymaBay has an option to receive a further $25 million within approximately two months of the completion of enrollment of CymaBay’s Phase 3 RESPONSE clinical trial. In exchange, CymaBay will make fixed payments spread over a six-year period based on regulatory approval in the U.S. or the E.U. after the first such regulatory approval is obtained, as well as pay fixed and capped sales milestones based on U.S. product sales. CymaBay has the ability to accelerate payment at a reduced amount upon regulatory approval and in the event of a change of control of CymaBay. CymaBay retains upside potential for seladelpar in the U.S. along with full worldwide commercial rights.

CymaBay is currently dosing patients in its Phase 3 RESPONSE clinical trial as well as its ASSURE open- label extension trial and other Phase 1 NDA-enabling clinical studies.

“We are excited to provide CymaBay with the capital needed to advance seladelpar through Phase 3 trials with the aim of bringing this important medicine to patients in real need,” said

Bali Muralidhar, Managing Partner at Abingworth. “This deal is a great example of the creative financing structures we look to form with innovative biopharma companies through ACCD2, our new clinical co-development fund.”

Perella Weinberg Partners and J. Wood Capital Advisors LLC acted as financial advisors to CymaBay on the transaction.

About Seladelpar

Seladelpar is a first-in-class oral, selective PPARδ agonist shown to regulate critical metabolic and liver disease pathways in indications with high unmet medical need. Preclinical and clinical data support its ability to regulate genes involved in bile acids synthesis, inflammation, fibrosis and lipid metabolism, storage and transport.

About RESPONSE

RESPONSE (NCT04620733) is a 52-week, placebo-controlled, randomized, global Phase 3 study to evaluate the safety and efficacy of seladelpar in patients with primary biliary cholangitis (PBC). Approximately 180 PBC patients will be randomized to seladelpar 10 mg/day, or placebo. Patients must have an inadequate response to UDCA (defined as a serum alkaline phosphatase level ≥ 1.67 x the upper limit of normal after at least 12 months of treatment) or an intolerance to UDCA to be eligible for the study. Patients who are inadequate responders to UDCA will continue their UDCA treatment during the study. The primary outcome measure will be the responder rate at 52 weeks, where a responder is defined as a patient who achieves an alkaline phosphatase level < 1.67 x the upper limit of normal with at least a 15% decrease from baseline and has a normal level of total bilirubin. Additional key outcomes of efficacy will compare the rate of normalization of alkaline phosphatase at 52 weeks and the level of pruritus at 6-months for patients with moderate to severe pruritus at baseline assessed by a numerical rating scale recorded with an electronic diary. To learn more, visit www.pbcstudies.com.

About CymaBay

CymaBay Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on improving the lives of people with liver and other chronic diseases that have high unmet medical need through a pipeline of innovative therapies. Our deep understanding of the underlying mechanisms of liver inflammation and fibrosis, and the unique targets that play a role in their progression, have helped us receive breakthrough therapy designation (U.S. Food and Drug Administration), PRIority MEdicines status (European Medicines Agency) and orphan drug status (U.S. and Europe) for seladelpar, a first-in-class treatment for people with primary biliary cholangitis (PBC). Our evidence-based decision-making and commitment to the highest quality standards reflect our relentless dedication to the people, families and communities we serve. To learn more, visit www.cymabay.com and follow us on Twitter and Linkedin.

About Abingworth

Abingworth is a leading transatlantic life sciences investment firm. Abingworth helps transform cutting-edge science into novel medicines by providing capital and expertise to top calibre management teams building world-class companies. Since 1973, Abingworth has

invested in 175 life science companies, leading to 44 M&As and 71 IPOs. Our therapeutic focused investments fall into three categories: seed and early-stage, development stage, and clinical co-development. Abingworth supports its portfolio companies with a team of experienced professionals at offices in London, Menlo Park (California), and Boston.

Cautionary Statements

Any statements made in this press release regarding the funding expected to be provided by Abingworth and payment schedule, as well as the potential for seladelpar to treat PBC and potentially improve clinical symptoms of the disease, the potential benefits to patients, and CymaBay's expectations and plans regarding its current and future clinical trials are forward looking statements that are subject to risks and uncertainties. Actual results and the timing of events regarding the funding and further development of seladelpar could differ materially from those anticipated in such forward-looking statements as a result of risks and uncertainties, which include, without limitation, risks related to: the agreement with Abingworth may be terminated by Abingworth under certain circumstances; there is no assurance that CymaBay will be able to meet its requirements under the Abingworth agreement; the success, cost and timing of any of CymaBay's product development activities, including clinical trials; effects observed in trials to date that may not be repeated in the future; any delays or inability to obtain or maintain regulatory approval of CymaBay's product candidates in the United States or worldwide; and the ability of CymaBay to obtain sufficient financing to complete development, regulatory approval and commercialization of its product candidates in the United States and worldwide. Additional risks relating to CymaBay are contained in CymaBay's filings with the Securities and Exchange Commission, including without limitation its most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 13, 2021, and other documents subsequently filed with or furnished to the Securities and Exchange Commission. CymaBay disclaims any obligation to update these forward-looking statements except as required by law.

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CYMABAY THERAPEUTICS

Source: CymaBay Therapeutics, Inc.