NewAmsterdam Pharma and the Menarini Group Sign Licensing Deal to Commercialize Obicetrapib in Europe

-- Combines NewAmsterdam's lead clinical program obicetrapib with Menarini's deep cardiovascular disease and regional expertise --

-- Total deal value of over €1 billion; including €142.5 million upfront payment and committed R&D funding plus potential milestones and double-digit royalties on net product sales in Europe --

-- Obicetrapib is a next-generation oral, low-dose and once-daily CETP inhibitor for which promising safety and strong LDL-lowering efficacy has been observed in patients with dyslipidemia through Phase 2b --

Naarden, the Netherlands, Miami, USA and Florence, Italy; June 28, 2022 – NewAmsterdam Pharma (NewAmsterdam), a clinical-stage company focused on the research and development of transformative oral therapies for major metabolic diseases, and the Menarini Group (Menarini), an Italy-based, privately held, international pharmaceutical company, today announced an exclusive license agreement for the commercialization of obicetrapib, if approved, in Europe, either as a monotherapy or as part of a fixed dose combination with ezetimibe, for cardiovascular diseases. Obicetrapib is NewAmsterdam's next-generation oral, low-dose and once-daily cholesteryl ester transfer protein (CETP) inhibitor therapeutic candidate, for which a promising safety and efficacy profile as an LDL-lowering adjunct to maximally tolerated statin therapy in patients with dyslipidemia has been observed through Phase 2b trials. Under the collaboration agreement, NewAmsterdam will retain all rights to commercialize obicetrapib, if approved, in the rest of the world, as well as rights to develop certain forms of obicetrapib for other diseases such as Alzheimer's disease.

"We are delighted to enter into this agreement with Menarini," said Michael Davidson, M.D., Chief Executive Officer of NewAmsterdam Pharma. "As we advance obicetrapib through late-stage clinical development, we believe now is the right time to begin laying the groundwork for our global product launch. Menarini is a leading pharmaceutical company with substantial cardiovascular expertise and the greatest share of voice among cardiologists, internists and general practitioners across major European markets, as well as strong relationships with key opinion leaders. We believe they are the right partner to accelerate efforts to maximize the delivery of obicetrapib, upon approval, to the millions of hyperlipidemia patients in Europe who are underserved by existing options."

The collaboration expands Menarini's existing cardiology portfolio of 18 products, which address the most widespread cardiometabolic diseases and aim to prevent and reduce risk factors associated with chronic conditions, with the goal of helping patients restore their quality of life.

"Obicetrapib, if approved, could radically alter the treatment landscape in cardiovascular disease by providing an effective and oral option for hyperlipidemia patients in Europe" said Elcin Barker Ergun, Chief Executive Officer of the Menarini Group. "As a leading company in cardiovascular treatments area, we find it an excellent fit to our portfolio and look forward to collaborating with NewAmsterdam Pharma to advance its development."

Subject to the terms of the agreement, NewAmsterdam will receive an upfront payment of €115 million, as well as €27.5 million in committed R&D funding, for a total of €142.5 million in committed consideration. NewAmsterdam will be eligible to receive up to €863 million in potential clinical, regulatory and commercial milestones, bringing the total potential deal value to €1,005.5 million. In addition, Menarini will pay NewAmsterdam tiered double-digit percentage royalties from the teens to mid-twenties on net sales of obicetrapib in Europe.

Pursuant to the terms of the agreement, NewAmsterdam will be responsible for further clinical development of obicetrapib and the parties will cooperate in regulatory activities to secure approval for the product. Menarini will be responsible for all commercialization activities in the licensed territory.

"This alliance exemplifies NewAmsterdam's strategy of engaging with the right partner at the right time with the right deal," said Lina Gugucheva, Chief Business Officer of NewAmsterdam Pharma. "In addition to Menarini's strong commercial credentials in the cardiovascular field in Europe, this agreement also brings in proceeds that we expect will substantially fund obicetrapib's development through planned Phase 3 data readouts, while allowing NewAmsterdam to retain substantial participation in the potential commercial opportunity in an important major market."

Advisors

Moelis & Company LLC is acting as financial advisor and Covington & Burling LLP is acting as legal advisor to NewAmsterdam Pharma. Goldman Sachs is acting as financial advisor to Menarini.

About Obicetrapib

Obicetrapib is a next-generation oral, low-dose and once-daily CETP inhibitor in development for lowering low-density lipoprotein cholesterol (LDL-c) and preventing major adverse cardiovascular events. More than 100 million people globally are not achieving LDL-c goals despite the current available standard of care. Obicetrapib was previously tested in ROSE and TULIP[1] randomized double-blind, placebo-controlled Phase 2 trials. Results from the ROSE trial, presented in November 2021 at the AHA Scientific Sessions, included observations that patients on statin therapy who received 5 mg of obicetrapib saw an LDL-c reduction of 42%. Patients who were part of the 10 mg cohort were observed to experience a 51% reduction versus baseline, while the placebo cohort was observed to experience a 7% reduction versus baseline. Both doses were observed to be well tolerated, with no serious adverse effects in the two cohorts and two serious AEs in the placebo arm. Currently, Obicetrapib is being tested in three Phase 3 trials, BROADWAY, BROOKLYN and PREVAIL, and a secondary Phase 2 trial, ROSE2. These studies are intended to examine obicetrapib as a combination therapy as well as its efficacy in adjunct to diet and a maximally tolerated lipid-lowering therapy, and reduction of major adverse cardiovascular events.

About NewAmsterdam Pharma

NewAmsterdam Pharma is a private clinical-stage biopharmaceutical company whose mission is to improve patient care in populations with metabolic diseases where traditional therapies have been unsuccessful or are not tolerated. NewAmsterdam is investigating obicetrapib, a next-generation oral, low-dose and once-daily CETP inhibitor, as the preferred LDL-c-lowering therapy for high-risk cardiovascular disease (CVD) patients. Results from NewAmsterdam's ROSE Phase 2b trial (presented at AHA Scientific Sessions in 2021) included observations that patients receiving obicetrapib 10mg experienced reduced LDL-c by 51% versus baseline in patients on statin therapy (vs. a 7% reduction in the placebo arm). Based in the Netherlands, NewAmsterdam was founded in 2019 by the venture capital firm Forbion and John Kastelein, and closed a $196M (€161M) Series A financing in January 2021 led by Forbion, Morningside Ventures and Ascendant BioCapital. For more information, please visit: www.newamsterdampharma.com.

About Menarini

The Menarini Group is a leading international pharmaceutical and diagnostics company, with a turnover of over $4 billion and over 17,000 employees. Menarini is focused on therapeutic areas with high unmet needs with products for cardiology, oncology, pneumology, gastroenterology, infectious diseases, diabetology, inflammation, and analgesia. With 18 production sites and 9 Research and Development centers, Menarini's products are available in 140 countries worldwide. For further information, please visit www.menarini.com.

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[1] Hovingh, G. K., Kastelein, J. J. P., van Deventer, S. J. H., Round, P., Ford, J., Saleheen, D., Rader, D. J., Brewer, H. B., & Barter, P. J. (2015). Cholesterol ester transfer protein inhibition by TA-8995 in patients with mild dyslipidaemia (TULIP): a randomised, double-blind, placebo-controlled phase 2 trial. In The Lancet (Vol. 386, Issue 9992, pp. 452–460). Elsevier BV. https://doi.org/10.1016/s0140-6736(15)60158-1

Forward-Looking Statements

Certain statements included in this press release that are not historical facts are forward-looking statements. Forward-looking statements generally are accompanied by words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “should,” “would,” “plan,” “predict,” “potential,” “seem,” “seek,” “future,” “outlook” and similar expressions that predict or indicate future events or trends or that are not statements of historical matters. These forward-looking statements include, but are not limited to, statements regarding estimates and forecasts of other financial and performance metrics and projections of market opportunity; expectations and timing related to the success, cost and timing of product development activities, including timing of initiation, completion and data readouts for clinical trials and the potential approval of NewAmsterdam’s therapeutic candidate; the size and growth potential of the markets for NewAmsterdam’s therapeutic candidate; the therapeutic and curative potential of NewAmsterdam’s therapeutic candidate; and NewAmsterdam’s expected cash runway. These statements are based on various assumptions, whether or not identified in this press release, and on the current expectations of NewAmsterdam’s management and are not predictions of actual performance. These forward-looking statements are provided for illustrative purposes only and are not intended to serve as and must not be relied on by anyone as a guarantee, an assurance, a prediction, or a definitive statement of fact or probability. Actual events and circumstances are difficult or impossible to predict and may differ from assumptions, and many are beyond the control of NewAmsterdam. These forward-looking statements are subject to a number of risks and uncertainties, including uncertainty regarding outcomes of NewAmsterdam’s ongoing clinical trials, particularly as they relate to regulatory review and potential approval for its therapeutic candidate and other business milestones; ability to negotiate definitive contractual arrangements with potential customers; the impact of competitive therapeutic candidates; ability to obtain a sufficient supply of materials; the impact of COVID-19; global economic and political conditions; and the effects of competition on NewAmsterdam’s business. If any of these risks materialize or NewAmsterdam’s assumptions prove incorrect, actual results could differ materially from the results implied by these forward-looking statements. There may be additional risks that NewAmsterdam does not presently know or currently believes are immaterial that could also cause actual results to differ from those contained in the forward-looking statements. In addition, forward-looking statements reflect NewAmsterdam’s expectations, plans, or forecasts of future events and views as of the date of this press release. NewAmsterdam anticipates that subsequent events and developments will cause NewAmsterdam’s assessments to change. However, while NewAmsterdam may elect to update these forward-looking statements at some point in the future, NewAmsterdam specifically disclaims any obligation to do so, except as required by law. These forward-looking statements should not be relied upon as representing NewAmsterdam’s assessments as of any date subsequent to the date of this press release. Accordingly, undue reliance should not be placed upon the forward-looking statements.

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