BioLineRx and Ayrmid Ltd. Enter into Exclusive License Agreement to Commercialize APHEXDA® (motixafortide) through Gamida Cell Ltd.

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– BioLineRx to receive $10 million upfront payment from Ayrmid Ltd. (parent company of Gamida Cell) plus up to $87 million in commercial milestones, as well as royalties on net sales ranging from 18% to 23% –

– BioLineRx retains rights to develop and commercialize motixafortide in solid tumors, including PDAC –

– BioLineRx received $9 million equity investment from certain funds managed by Highbridge Capital Management, LLC to support company's pipeline and expansion –

– Transactions enable significant reduction in BioLineRx's operational expenses and debt, and allow the company to focus on development activities in areas of high unmet need in oncology and rare diseases –

– BioLineRx will provide further corporate updates on its Q3 results conference call, which is scheduled for November 25 at 8:30 am ET –

TEL AVIV, Israel, Nov. 21, 2024 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, and Ayrmid Ltd. ("Ayrmid"), the parent company of Gamida Cell Ltd., today announced that on November 20, 2024, the companies entered into a license agreement for motixafortide (commercially sold in the U.S. as APHEXDA®), BioLineRx's FDA-approved stem cell mobilization agent indicated in combination with filgrastim (G-CSF) for collection and subsequent autologous transplantation in patients with multiple myeloma.

Under the terms of the agreement, BioLineRx granted Ayrmid an exclusive license to develop and commercialize APHEXDA (motixafortide) across all indications, excluding solid tumor indications, and in all territories other than Asia. BioLineRx previously granted an exclusive license agreement to Gloria Biosciences for APHEXDA (motixafortide) in the Asia region.

In exchange for the license, BioLineRx will receive a $10 million upfront payment and is also eligible to receive up to an additional $87 million of potential commercial milestones, plus royalties ranging from 18% to 23% on net sales of APHEXDA.

Ayrmid will add APHEXDA to its commercial portfolio, which also includes Gamida Cell's OMISIRGE®, the first and only FDA-approved, nicotinamide (NAM)-modified cell therapy for patients with hematologic malignancies in need of a stem cell transplant. As part of this transaction, Ayrmid expects to transition certain members of BioLineRx's U.S.-based commercial organization, who will support both stem cell transplant drugs.

Through this transaction, BioLineRx will significantly reduce its long-term debt and operational expenses, which will be reviewed in detail during the company's upcoming Q3 results conference call and webcast.

BioLineRx also entered into a share purchase agreement for a $9 million equity investment from certain funds managed by Highbridge Capital Management, LLC. This investment and the combined future potential commercial milestones from licensing agreements with Ayrmid and Gloria Biosciences, as well as royalties on net sales, are expected to provide a strong foundation for BioLineRx to advance its pipeline and identify potential additional assets for development. The equity investment is expected to close today, November 21, 2024, subject to the satisfaction of customary closing conditions.

BioLineRx will continue the development of motixafortide for pancreatic ductal adenocarcinoma (PDAC) through meaningful collaborations, including an active Phase 2b PDAC study led by Columbia University, and supported equally by BioLineRx and Regeneron, as well as a planned Phase 2b PDAC study in China led by Gloria Biosciences.

"Since APHEXDA's launch last year, patients and transplant centers continue to see the tremendous benefits it can provide, and I could not be prouder of our commercial organization that has proven its value," stated **Philip Serlin, Chief Executive Officer of BioLineRx**. "Our agreement with Ayrmid, and their vision of creating a strong commercial transplant portfolio, makes them the ideal partner to realize APHEXDA's full commercial potential. BioLineRx will now leverage its proven expertise in drug development, with a continued focus on oncology and rare diseases. This new path forward aligns with our core strengths and allows us the opportunity to create enduring value for all stakeholders."

Dr. Joe Wiley, Chief Executive Officer of Ayrmid Ltd, added, "APHEXDA represents a significant advancement in improving the lives of multiple myeloma patients as they progress along the stem cell transplant journey. APHEXDA complements our existing portfolio by supporting OMISIRGE's growth, doubling our transplant portfolio, and enhancing the capabilities Gamida Cell has already established in cell therapy. Our growing momentum positions us well for continued expansion in the U.S. and beyond, marking a key step in our journey as we continue to build on our success, strengthen our commitment to the transplant community, and execute our long-term strategy."

The equity investment offering is being made by BioLineRx pursuant to its shelf registration statement on Form F-3 (File No. 333-276323) previously filed with the Securities and Exchange Commission (the "SEC") and declared effective by the SEC on January 5, 2024, and only by means of a prospectus and prospectus supplement. A final prospectus supplement and accompanying prospectus relating to the offering will be filed with the SEC

and will be available on the SEC's web site at www.sec.gov.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

MTS Health Partners, L.P. served as the exclusive financial advisor to BioLineRx Ltd. in connection with the transaction.

Moelis & Company LLC served as the exclusive financial advisor to Ayrmid Ltd. in connection with the transaction.

BioLineRx Third Quarter Results Conference Call and Webcast
BioLineRx will report its third quarter 2024 results on November 25, 2024. To access the conference call, please dial +1-888-281-1167 from the U.S. or +972-3-918-0685 internationally. A live webcast and a replay of the call can be accessed through the event page on the Company's website. Please allow extra time prior to the call to visit the site and download any necessary software to listen to the live broadcast. The call replay will be available approximately two hours after completion of the live conference call. A dial-in replay of the call will be available until November 27, 2024; please dial +1-888-295-2634 from the US or +972-3-925-5904 internationally.

About Ayrmid Ltd. and Gamida Cell Ltd
Ayrmid Ltd. is the parent company of Gamida Cell Ltd. Gamida Cell is a cell therapy pioneer working to turn cells into powerful therapeutics. The company's proprietary nicotinamide (NAM) technology leverages the properties of NAM to enhance and expand cells, creating allogeneic cell therapy products and candidates that are potentially curative for patients with hematologic malignancies. These include OMISIRGE® (omidubicel-onlv), an FDA-approved nicotinamide modified allogeneic hematopoietic progenitor cell therapy. Gamida Cell operates as a wholly owned subsidiary of Ayrmid Limited, a UK entity. For additional information, please visit www.gamida-cell.com or follow Gamida Cell on LinkedIn, X, Facebook or Instagram.

About Highbridge Capital Management
Founded in 1992, Highbridge Capital Management, LLC ("Highbridge") is a global alternative investment firm offering differentiated credit and volatility focused solutions across a range of liquidity and investment profiles, including hedge funds, drawdown vehicles, and co-investments. The firm seeks to generate attractive risk-adjusted returns for sophisticated investors, which include financial institutions, public and corporate pension funds, sovereign wealth funds, endowments and family offices. Highbridge is headquartered in New York, with a research presence in London. In 2004 Highbridge established a strategic partnership with J.P. Morgan. Highbridge has over $4 billion in assets under management, as of April 1, 2024, and holds meaningful investments across the global healthcare and life sciences spectrum.

About BioLineRx
BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX) is a biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases. The company's first approved product is APHEXDA® (motixafortide), with an indication in the U.S. for stem cell mobilization for autologous transplantation in multiple myeloma, which is being developed and commercialized by Ayrmid Ltd. (globally, excluding Asia) and Gloria Biosciences (in Asia). BioLineRx is utilizing its end-to-end expertise in development, regulatory affairs, manufacturing and commercialization to advance its innovative pipeline and ensure life-changing discoveries move beyond the bench to the bedside.

Learn more about who we are, what we do, and how we do it at www.biolinerx.com, or on Twitter and LinkedIn.

Cautionary Note Regarding Forward-Looking Statements (BioLineRx)
Various statements in this release concerning BioLineRx's future expectations constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," and "would," and describe opinions about future events. These include statements regarding management's expectations, beliefs and intentions regarding, among other things, the potential success of the license agreement with Ayrmid, expectations with regard to clinical trials of motixafortide, statements relating to the equity investment offering, including as to the consummation of the offering described above, the expected gross proceeds therefrom and the timing of the closings of the offering and the license agreement. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of BioLineRx to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Factors that could cause BioLineRx's actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: the initiation, timing, progress and results of BioLineRx's preclinical studies, clinical trials, and other therapeutic candidate development efforts; BioLineRx's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; whether BioLineRx's collaboration partners will be able to execute on collaboration goals in a timely manner; whether the clinical trial results for APHEXDA will be predictive of real-world results; BioLineRx's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of BioLineRx's therapeutic candidates, including the degree and pace of market uptake of APHEXDA for the mobilization of hematopoietic stem cells for autologous transplantation in multiple myeloma patients; whether access to APHEXDA is achieved in a commercially viable manner and whether APHEXDA receives adequate reimbursement from third-party payors; BioLineRx's ability to establish, operationalize and maintain corporate collaborations; BioLineRx's ability to integrate new therapeutic candidates and new personnel; the interpretation of the properties and characteristics of BioLineRx's therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; the implementation of BioLineRx's business model and strategic plans for its business and therapeutic candidates; the scope of protection BioLineRx is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; estimates of BioLineRx's expenses, future revenues, capital requirements and its needs for and ability to access sufficient additional financing, including any unexpected costs or delays in the commercial launch of APHEXDA; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and BioLineRx's industry; statements as to the impact of the political and security situation in Israel on BioLineRx's business; and the impact of the COVID-19 pandemic, the Russian invasion of Ukraine, the declared war by Israel against Hamas and the military campaigns against Hamas and other terrorist organizations, which may exacerbate the magnitude of the factors discussed above. These and other factors are more fully discussed in the "Risk Factors" section of BioLineRx's most recent annual report on Form 20-F filed with the Securities and Exchange Commission on March 26, 2024. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

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Omisirge® (omidubicel-onlv) Indication
Omisirge is approved in the US for use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection. Please see the full PI, including boxed warning, here

Logo - https://mma.prnewswire.com/media/2154863/4547338/BioLineRx_Ltd_Logo.jpg

View original content:https://www.prnewswire.com/news-releases/biolinerx-and-ayrmid-ltd-enter-into-exclusive-license-agreement-to-commercialize-aphexda-motixafortide-through-gamida-cell-ltd-302312746.html

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