



BioLineRx Announces Clinical Research Collaboration to Investigate Combination of BL-8040 with Atezolizumab in Multiple Oncology Indications

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Cancer immunotherapy collaboration with Genentech includes several Phase 1b combination studies for multiple solid tumor indications and AML

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BioLineRx Ltd. (NASDAQ/TASE: BLRX) today announced that it has entered into a collaboration with Genentech, a member of the Roche Group, to support several Phase 1b studies investigating BioLineRx's BL-8040 in combination with Atezolizumab, Genentech's anti-PDL1 cancer immunotherapy, in multiple cancer indications. The Phase 1b studies will evaluate the clinical response, safety and tolerability of the combination of these therapies, as well as multiple pharmacodynamic parameters, in hematologic malignancies and solid tumors.

Under the agreement, Genentech will sponsor and conduct several Phase 1b trials in multiple solid cancer indications. In addition, BioLineRx will sponsor and conduct a Phase 1b study in acute myeloid leukemia (AML) patients. The studies are planned as open-label, multicenter, single-arm trials designed to evaluate the safety and efficacy of the combination of BL-8040 and Atezolizumab. Upon completion of the studies, both parties will have the option to expand the collaboration to include a pivotal registration study. Additional details of the collaboration were not disclosed.

BL-8040, BioLineRx's lead oncology platform, is a CXCR4 antagonist that has been shown in several clinical trials to be a robust mobilizer of immune cells and to be effective at inducing direct tumor cell death. Additional findings in the field of immuno-oncology suggest that CXCR4 antagonists may be effective in inducing the migration of anti-tumor T cells into the tumor micro-environment. Atezolizumab is a humanized monoclonal antibody designed to bind with a protein called PD-L1. Atezolizumab is designed to bind to PD-L1 expressed on tumor cells and tumor-infiltrating immune cells, blocking its interactions with both PD-1 and B7-1 (CD80) receptors. By inhibiting PD-L1, Atezolizumab may enable the activation of T cells, whose migration into the tumor may be enhanced by BL-8040.

"This collaboration agreement in multiple cancer indications with Genentech marks our second collaboration with a world leader in cancer immunotherapy for the combination of BL-8040 with an approved immune checkpoint inhibitor," stated Philip Serlin, Chief Financial and Operating Officer of BioLineRx. "Immune checkpoint inhibitors are a new class of promising drugs that have revolutionized anti-cancer treatment; however, it is becoming clear that certain tumor types will require a combination of immunotherapy with other classes of drugs. We are hopeful that the combination of BL-8040 and Atezolizumab will demonstrate the potential to expand the benefit of immunotherapy to cancer types currently resistant to cancer immunotherapy treatments."

About BL-8040

BL-8040 is a short peptide for the treatment of acute myeloid leukemia, solid tumors, and certain hematological indications. It functions as a high-affinity antagonist for CXCR4, a chemokine receptor that is directly involved in tumor progression, angiogenesis, metastasis and cell survival. CXCR4 is over-expressed in more than 70% of human cancers and its expression often correlates with disease severity. In a number of clinical and pre-clinical studies, BL-8040 has shown robust mobilization of cancer cells from the bone marrow, thereby sensitizing these cells to chemo- and bio-based anti-cancer therapy, as well as a direct anti-cancer effect by inducing apoptosis. In addition, BL-8040 has also demonstrated robust stem-cell mobilization, including the mobilization of colony-forming cells, and T, B and NK cells. BL-8040 was licensed by BioLineRx from Biokine Therapeutics and was previously developed under the name BKT-140.

About BioLineRx

BioLineRx is a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates. The Company in-licenses novel compounds, primarily from academic institutions and biotech companies based in Israel, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's leading therapeutic candidates are: BL-8040, a cancer therapy platform, which has successfully completed a Phase 2a study for relapsed/refractory AML, is in the midst of a Phase 2b study as an AML consolidation treatment, and has recently initiated a Phase 2 study in stem cell mobilization for allogeneic transplantation; and BL-7010 for celiac disease and gluten sensitivity, which has successfully completed a Phase 1/2 study. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates; a collaboration agreement with MSD (known as Merck in the US and Canada) to run a Phase 2a study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®; and has recently signed a collaboration agreement with Genentech, a member of the Roche Group, to investigate several Phase 1b combination studies in multiple solid tumor indications and AML using the combination of BL-8040 and Genentech's Atezolizumab.

For additional information on BioLineRx, please visit the Company's website at <http://www.biolinerx.com>, where you can review the Company's SEC filings, press releases, announcements and events. BioLineRx industry updates are also regularly updated on [Facebook](#), [Twitter](#), and [LinkedIn](#).

Various statements in this release concerning future expectations constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "may," "expects," "anticipates," "believes," and "intends," and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. These and other factors are more fully discussed in the "Risk Factors" sections of recent annual reports filed by the parties to this release. In addition, any forward-looking statements represent the parties' views only as of the date of this release and should not be relied upon as representing their views as of any subsequent date. The parties do not assume any obligation to update any forward-looking statements unless required by law.

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