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ASIA EDITION

BioLineRx gets Orphan Drug Designation for its pancreatic cancer drug

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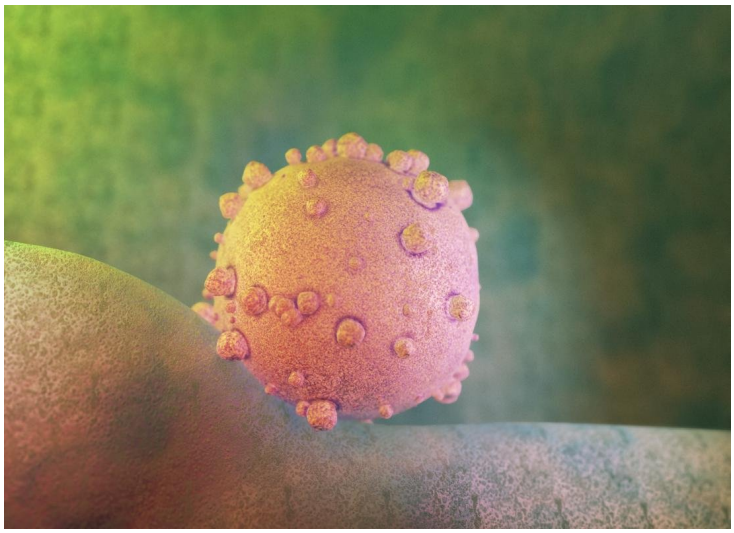

BioLineRx Ltd., an Israeli clinical-stage biopharmaceutical company focused on oncology, announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to its lead oncology candidate, BL-8040, for the treatment of pancreatic cancer.

"Orphan Drug Designation in pancreatic cancer is a very important milestone in the development plan of BL-8040, and joins previously approved orphan designations by the FDA for BL-8040 in AML and stem-cell mobilization," stated Philip Serlin, Chief Executive Officer of BioLineRx. "Despite advances in the treatment of various cancers with immune checkpoint inhibitors, pancreatic cancer is refractory to these treatment options, and remains an area of significant unmet medical need. We have previously reported encouraging clinical data supporting the potential of BL-8040 as part of an immunotherapy combination treatment in pancreatic cancer, and we look forward to top-line results from our ongoing pancreatic clinical studies later this year."

BL-8040 is currently being investigated in clinical studies for the treatment of pancreatic cancer under two separate immuno-oncology collaborations – one with Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the United States and Canada), and a second collaboration with Genentech, a member of the Roche Group.

Orphan Drug Designation by the FDA entitles BioLineRx to seven years of market exclusivity for the use of BL-8040 for the treatment of pancreatic cancer, if approved, plus significant development incentives, including tax credits related to clinical trial expenses, an exemption from the FDA-user fee, and FDA assistance in clinical trial design.