

Alligator Bioscience submits CTA for the mitazalimab Phase II study OPTIMIZE-1

Lund, Sweden, December 28, 2020 – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announced that it has submitted a CTA (Clinical Trial Authorization) application to the relevant regulatory authorities to start a Phase II efficacy study of its wholly-owned CD40 targeting antibody mitazalimab.

The upcoming Phase II study OPTIMIZE-1 is an open-label, multi-center study assessing the clinical efficacy of mitazalimab in combination with chemotherapy (mFolfinirox) in patients with metastatic pancreatic cancer. The OPTIMIZE-1 study will be performed at several clinics in Europe and encompass up to a total of 66 patients. Inclusion of the first patient is planned during the first half of 2021 and will begin with a run-in period to determine the best dose for the combination with chemotherapy.

“The CTA submission is an important milestone for Alligator, as we are now entering clinical Phase II for the first time. With best-in-class benchmark data presented for mitazalimab during the autumn, I believe that OPTIMIZE-1 has great potential to deliver robust efficacy results in pancreatic cancer”, said Per Norlén, CEO of Alligator Bioscience.

The mitazalimab drug candidate has previously reported positive clinical data from two Phase I studies, one performed by Alligator, one performed by Janssen Biotech Inc., displaying a manageable safety profile as well as early signs of efficacy.

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The information was submitted for publication, through the agency of the contact person set out above, at 11:00 a.m. CET on December 28, 2020.

About Alligator Bioscience

Alligator Bioscience AB is a clinical-stage biotechnology company developing tumor-directed immuno-oncology antibody drugs. Alligator’s pipeline includes the two key assets ATOR-1017 and mitazalimab. Furthermore, there are two partnered assets: ALG.APV-527 in co-development with Aptevo Therapeutics Inc. and AC101 in clinical development by Shanghai Henlius Biotech Inc. In addition, the company has developed a novel concept for more patient-specific immunotherapy: Neo-X-Prime. Alligator’s shares are listed on Nasdaq Stockholm (ATORX). The Company is headquartered in Lund, Sweden. For more information, please visit www.alligatorbioscience.com.