

Tak lands at Candela, with plans to speed up development of immunotherapy's play late-stage assets

BY STEPHEN HANSEN, ASSOCIATE EDITOR

Oncolytic virus company Candela has bolstered its executive team with a quartet of industry veterans headlined by new CEO Paul Peter Tak, a biotech entrepreneur and GSK veteran who plans to raise venture money to accelerate development of the company's late-stage pipeline while adding discovery programs.

Boston-based Candela Therapeutics, formerly known as Advantagene Inc., is developing two different oncolytic virus platforms with the most advanced program in Phase III testing to treat prostate cancer.

But with the majority of the company's more than 20 years of existence spent subsisting on federal funding, one of Tak's primary focuses will be to accelerate the pace of development.

"There are not many biotech companies out there almost in stealth mode that are in Phase III, pre-IPO in cancer immunotherapy," Tak told BioCentury. "I thought this is where I can have an impact with my background in academia, pharma and biotech, to help build this business ready for the next stage."

Tak was most recently president and CEO of Kintai Therapeutics and a venture partner at Flagship Pioneering. Before that he was SVP and chief immunology officer at GlaxoSmithKline plc (LSE:GSK; NYSE:GSK).

Over the past two-plus months he's added three other executives to the team. John Canepa was named Candela's CFO. He was most recently CFO at degenerative disease company Frequency Therapeutics Inc. (NASDAQ:FREQ), which last year raised \$88.6 million in an IPO.

Also joining Candela is CBO Nathan Caffo and Chief Regulatory Officer Susan Stewart. Caffo was previously CBO at immuno-oncology company ALX Oncology Holdings Inc. (NASDAQ:ALXO), while Stewart, who serves as an independent consultant, is also chief regulatory officer at Kaleido Biosciences Inc. (NASDAQ:KLDO).

Candela's prior CEO, founder Estuardo Aguilar-Cordova, has become CSO, while Laura Aguilar remains CMO.

As Tak continues to expand Candela's management team, he plans to begin fund-raising to add fresh capital to the company. Candela

was founded in 1999 but didn't raise its first institutional financing round until 2016, with subsequent series B and C rounds last year that bring total venture capital raised to \$67.6 million.

Tak said that as the company has been efficient with its capital there's still plenty of cash to execute on existing programs, but he aims to accelerate the development of the pipeline while adding new discovery programs.

Candela's lead program is aglatimagene besadenovec (CAN-2409), a replication-deficient oncolytic adenovirus that delivers the HSV thymidine kinase gene to cancer cells. Patients are then dosed with valacyclovir, which the locally expressed thymidine kinase enzyme converts into a toxic metabolite, killing the tumor cells and creating a pro-inflammatory microenvironment that leads to increased T cell infiltration.

Aglatimagene is in a Phase III trial for intermediate or high-risk prostate cancer patients and a Phase II trial for prostate cancer patients on active surveillance. The same program is being tested in three other indications: a Phase III trial starting next year in first-line glioblastoma multiforme (GBM); and Phase II studies in pancreatic cancer and non-small cell lung cancer (NSCLC).

Candela's second platform is a novel HSV vector. The lead program there is CAN-3110, a replication-competent HSV oncolytic virus that can self-amplify and is in Phase I testing to treat recurrent glioblastoma.

Tak said data from the Phase III prostate cancer trial is expected in 2023, while next year Candela expects Phase II data from the active surveillance prostate cancer trial and the NSCLC trial; and Phase I data for aglatimagene plus Opdivo nivolumab in newly diagnosed GBM and for CAN-3110 in recurrent glioblastoma.

Tak said he's also starting a discovery program of novel HSV oncolytic viruses that can modulate the tumor microenvironment. Other companies such as PsiOxus Therapeutics Ltd., Replimune Group Inc. (NASDAQ:REPL) and Transgene S.A. (Euronext:TNG) have "armed" oncolytic virus platforms that carry transgenes that express molecules that can modulate the tumor locally.

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