BetterLife spotlights busy 2021 product development roadmap for its psychedelic products, coronavirus nebulizer and AP-001 cream

BetterLife Pharma Inc (CSE:BETR) (OTCQB:BETRF) (FRA:NPAU) told investors Tuesday that the firm’s plans for 2021 hinge on developing three novel therapeutic products, which address “significant unmet needs” with multi-billion dollar market potential.

“The last six months of 2020 have been very transformational for BetterLife, filled with milestones, an appreciating stock price and the development of a future roadmap to increase growth and shareholder value,” said BetterLife CEO Ahmad Doroudian in a corporate update.

“We are aggressively developing cutting edge next generation psychedelic products, such as TD-0148A, to become a leader in an emerging market with a projected $6.85 billion value by 2027 alone.”

READ: BetterLife says its AP-003 coronavirus treatment has similarities with Pfizer’s vaccine

While providing an overview, Doroudian noted that the biotech firm is also seeing “great progress” in its development of AP-003 for the treatment of pandemic respiratory viral infections and AP-001, a cream formulation for the treatment of human papilloma virus (HPV).

“We are very much looking forward to our meeting with the US Food and Drug Administration (FDA) in early March. Today, I am proud and excited to share this roadmap for 2021 and beyond with the past, present and future shareholders,” he added.

In January, BetterLife applied for patent protection for its new 2-Bromo-LSD (TD-0148A) formulations to treat severe depression, post-traumatic stress disorder (PTSD) and substance dependencies. The initial clinical focus will be on treatment-resistant depression. 2-Bromo-LSD is a nontoxic second-generation LSD-derived molecule that mimics the therapeutic potential of LSD, without the psychedelic effects or hallucinations.

“BetterLife is planning to have a pre-IND meeting with the FDA in Q2 2021, with the goal to file an IND and initiate a Phase 1 clinical trial in healthy volunteers in this calendar year,” said the company.

Subject to health regulatory approvals, the firm is planning independent investigator studies in parallel with the IND filing to begin in the first or second quarter of 2021.

BetterLife’s recent C$10 million acquisition of the assets of Transcend Biodynamics makes it the only company able to synthesize 2-Bromo-LSD utilizing a patented process which obviates the need to first synthesize LSD-25 — eliminating the regulatory barriers of working with a Schedule 1 substance.
BetterLife said it will conduct process development, scale-up and GMP manufacturing of TD-0148A during this calendar year, leading up to the IND. It will also carry out the IND-enabling preclinical studies in the same time frame.

Separately, BetterLife's AP-003, an interferon alpha-2b (IFN-a2b) inhalation formulation is being developed for treating respiratory viral infections, with the focus on early-stage coronavirus (COVID-19). AP-003 can be used by the patient at home with a nebulizer. Based on FDA guidance, the biotech has initiated the preclinical IND-enabling studies, with the goal to file the IND by the third quarter of 2021.

Subject to health regulatory approvals, BetterLife said it is also considering AP-003 trials in COVID-19 patients in "Q1-Q2 2021 in ex-North American territories, using previously manufactured AP-003."

BetterLife is advanced in its process development and scale-up of its proprietary IFN-a2b manufacturing, which it aims to complete by end of Q1 2021. A bridging clinical trial between the old and new manufactured AP-003 will also be conducted to enable use of the ex-North American data as supportive for the US IND. The firm hopes to be able to initiate a registration directed study in the US following the IND.

In the meantime, BetterLife's AP-001, a patent-protected IFN-a2b cream formulation is being developed for the treatment of human papillomavirus (HPV) induced high-grade cervical intra-epithelial neoplasia, the precursor to cervical cancer. Current treatments for this indication are all invasive with risk of side effects.

AP-001 is being developed as a patient self-administered (once-daily) intra-vaginal cream as a six-week treatment. By Q3 of 2021, the biotech said it plans to have "completed process development and scale-up of the AP-001 cream and initiate GMP manufacturing."

BetterLife plans to have a pre-IND meeting with the FDA in the third quarter of 2021, and initiate the IND-enabling studies with the goal to file an IND by the first quarter of 2022.

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