BIOCENTURY

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EMERGING COMPANY PROFILE

EpyGenix: Fishing for best in class in epilepsy

BY STEPHEN HANSEN, ASSOCIATE EDITOR

EpyGenix has leveraged its animal model of Dravet syndrome to identify three repurposed molecules that have shown high levels of preclinical efficacy. The biotech is hoping the well-established safety profiles of each molecule gives them best-in-class potential.

EpyGenix Therapeutics Inc.'s pipeline was identified using a zebrafish screening model created in the lab of Scott Baraban at the University of California San Francisco.

EpyGenix Chairman Alex Yang told BioCentury that Baraban's group created the SCN1A-mutant zebrafish model because the gene is responsible for about 85% of Dravet syndrome cases. His lab then conducted an *in vivo* phenotypic screen of more than 3,500 known compounds, four of which showed a strong efficacy signal.

Yang is also CEO of Hong Kong-based MStone Partners. EpyGenix is led by co-founder and CEO Hahn-Jun Lee, who has co-founded several other biotechs in MStone's portfolio. Fellow co-founder Baraban is on the company's scientific advisory board.

Yang said further work by Baraban's lab found that what tied the four programs together was their common mechanism of modulating serotonin 5-HT2B receptor activity.

What helped validate the findings, he said, was that one of the four drugs was fenfluramine, which is already approved in a low-dose formulation as Fintepla from Zogenix Inc. (NASDAQ:ZGNX) to treat Dravet syndrome.

EpyGenix is pursuing the other three as potential treatments for Dravet and other rare forms of epilepsy. EPX-100 is clemizole, an anti-histamine that was on the market for 30 years until the 1970s when it was withdrawn for commercial reasons. EPX-200 is lorcaserin, which Eisai Co. Ltd. (Tokyo:4523) and Arena Pharmaceuticals Inc. (NASDAQ:ARNA) marketed as Belviq to treat obesity until its withdrawal from the market last year due to an identified cancer risk, and EPX-300 is trazodone, an antidepressant that was first approved in 1981.

COMPANY PROFILE
EPYGENIX THERAPEUTICS INC.
Paramus, N.J.

Technology: Zebrafish disease model of Dravet syndrome

Origin of technology: University of California San Francisco (UCSF)

Disease focus: Neurology

Clinical status: Phase II

Founded: 2016 by Hahn-Jun Lee and Scott Baraban

Academic collaborators: UCSF

Corporate partners: None

Number of employees: 2

Funds raised: $25 million

Investors: MStone Partners, Youngpoong Pharmaceutical Co. Ltd., undisclosed family offices and individual investors

CEO: Hahn-Jun Lee

Patents: 7 patents issued covering method of use and composition of matter

Yang argued the advantage is that each has a well-established safety profile, meaning EPX-200 and EPX-300 can progress directly into Phase III trials and pursue approval via the 505(b)2 pathway.

EPX-100 is taking a longer route, but could generate more value for the biotech. Because clemizole hadn't been on the market since the 1970s, "FDA said those data are a bit old. If you do the full animal studies and the Phase I studies, then you can achieve new chemical entity status," Yang said.

He said the key for EpyGenix will be to demonstrate that the compounds have a differentiated safety profile versus available therapies. According to Yang, EPX-100 has the cleanest profile of the three, with over 30 years of market safety data showing no serious adverse events, combined with animal toxicology and

Phase I data that did not identify any adverse events other than mild grogginess.

Fintepla has a black box warning cautioning against a risk for valvular heart disease and pulmonary arterial hypertension (PAH). Epidiolex cannabidiol, which is also marketed for Dravet and another rare epilepsy, Lennox-Gastaut syndrome (LGS), has warnings on its label for risk of increased liver enzymes. Epidiolex is marketed by GW Pharmaceuticals plc, which was acquired by Jazz Pharmaceuticals plc (NASDAQ:JAZZ) for $7.2 billion.

Yang said EpyGenix's Phase II trial of EPX-100 had a protocol amendment to increase the enrollment from 24 Dravet syndrome patients to 50 evaluable patients, which could help the company convert the trial into a pivotal study. Data from the Phase II study are expected in 2Q22 and, pending FDA discussions, the drug could be launched as early as 2023.

EPX-200 and EPX-300 each must also address safety issues of their legacy drugs — such as the increased cancer risk that led to lorcaserin being pulled from the market. But the biotech hopes the totality of the safety data combined with a strong efficacy profile could position each of them as a therapeutic option in rare epilepsy indications.

EpyGenix expects to start Phase III trials for both molecules in 1H22.

Yang said competition from RNA and gene therapy candidates in Dravet from companies such as Stoke Therapeutics Inc. (NASDAQ:STOK) and Encoded Therapeutics Inc. wouldn't necessarily steal market share as most patients require more than one type of anti-epileptic therapy.

Turning to financing, Yang said that EpyGenix will pursue an acquisition or an IPO, either via a traditional listing or a SPAC, once the EPX-100 data are in hand next year.

"We think the right time to go for an IPO is when we have the data on clemizole," he said. The hope is that the company can come to the public markets with a molecule that has a best-in-class profile with both better efficacy and safety. "That will really set us apart," he said.

TARGETS

SCN1A (Nav1.1) – Sodium voltage-gated channel alpha subunit 1

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