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BioPharmX to consider out-licensing acne drug upon well progressed Phase II to begin 1H16 – exec

BioPharmX (NYSEMKT:BPMX) will evaluate out-licensing its acne treatment BPX-01 once its imminent Phase II trial has reached mid-to-late stages, said company president Anja Krammer. BioPharmX hopes to initiate the trial in 1H16, with a study duration of approximately 12-18 months, she said.

BioPharmx will use this time to consider whether it wishes to invest in BPX-01's Phase III progression, said Krammer. BPX-01's is in the process of its IND submission, she said.

BPX-01 is the first and only stable hydrophilic topical gel with fully solubilised minocycline for the treatment of acne, according to a company press release.

Krammer declined to comment on the potential circumstances that would influence the company's out-licensing decisions beyond saying each possible partner will be considered. Its supplement product, Violet Iodine for the alleviation of fibrocystic breast symptoms, was commercialised inhouse, she added.

BioPharmX develops innovative drug delivery products with patented platform technologies, and is focused on the areas of dermatology and women's health. It also develops supplement and OTC products, according to the company website.

BioPharmX has partnering meetings scheduled for the JP Morgan conference next week (11-14 January) in San Francisco, California and the American Academy of Dermatology meeting (4-8 March) in Washington D.C, said Krammer. It is also in ongoing, early stage discussions with numerous parties, she said, adding BioPharmX is open to further partnering approaches. Ideal commercial partners would be dermatology players, said Krammer.

BPX-01 has global appeal and could benefit patients in the US, EU and Asia, therefore all regions would be considered, said Krammer. Partner size is less important than marketing delivery capability, she said.

BioPharmX would seek a traditional dermatology out-licensing deal, consisting of an upfront payment with performance-based milestones, including clinical, regulatory and commercial, as well as royalty payments, said Krammer. If the company chooses to commercialise internally, however, it will partner with a CMO specialising in topical drug manufacturing for high-volume production, said Krammer.

BPX-01's Phase II trial will be conducted in the US with a Phase IIa study of approximately 30 patients and Phase IIb of around 120-150, said Krammer.

A CRO and CMO have been appointed for the trials, said Krammer, declining to name them. The CRO is the oldest and most established dermatology CRO in the US, that typically executes 100-150 trials a year, she said. The CMO is mid-sized, US based, with over 75 years of experience in manufacturing sterile and non-sterile semi-solid and liquid dosage formulations, said Krammer.

Once BPX-01 has completed its Phase II trial, BioPharmX will reevaluate its in-licensing opportunities, said Krammer. The company is small and its current focus is BPX-01's clinical progression, said Krammer. BioPharmx will seek to in-license dermatology and women's health technologies as both indications consist of large patient populations with unmet treatment needs, she said.

BioPharmX has a market cap of USD 31m.

by Alexandra Thompson in London

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Drug(s)
*BPX01

Topic
Partnerships/Licensing

Event Calendar
Phase II Initiation

Indications
Acne

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USA

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