Integral BioSystems Receives Notice of Divisional Patent Allowance from USPTO for Sustained Drug Delivery Platform

The USPTO has issued a Divisional Patent Allowance for Integral BioSystems' NanoM™, the firm's sustained release technology platform

BEDFORD, MASSACHUSETTS, US, February 23, 2019 /EINPresswire.com/ -- Bedford, MA-based drug development firm Integral BioSystems has received a Divisional Patent notice of allowance from the USPTO on one of its flagship inventions, NanoM™, "Methods and Biocompatible Compositions to Achieve Sustained Drug Release in the Eye", United States Patent #9931306, issued on April 3, 2018.

> This divisional patent allowance greatly expands the number of patent-protected fields of use for NanoM™"
>
> *Dr. Shikha Barman*

Developed as a drug delivery platform for the formulation of new chemical entities as well as already-approved drugs in a 505(b)2 environment, the patented technology is a novel, patented, differentiated and improved delivery approach for administering sustained-release medications, both small molecules and biologics to ocular and other tissue types, both as therapies adjunct to surgical interventions as well as stand-alone sustained release drug therapies in ophthalmology. The technology is also applicable to otology, intranasal, buccal, sublingual, urology and other accessible tissue spaces.

The divisional patent covers broad embodiments of a drug-containing nanostructured wafer-based platform technology, as well as injectable, polymeric microencapsulates. The latter have novel surface characteristics that allow them to be remain dispersed after injection into a tissue space (such as the vitreous humor). This is a major improvement upon the current state-of-the-art in polymeric microspheres, which tend to aggregate into a mass when injected in tissue, leading to unpredictable release rates. This is a major issue, since the aggregated, clumped microspheres behave like a much larger delivery system, having release rates dependent on the dimensions and characteristics of the aggregated mass. As a result, the shape and internal characteristics of the aggregates are unpredictable and can vary with each injection. This leads to variability and unpredictability of drug pharmacokinetics. The novel nano- and micro-structured encapsulates offer improvements to this critical issue, by specific surface characteristics imparted by process treatments.

The additional claims allowed in this divisional patent extend ways to sustain release of therapeutics, both small molecules and biologics, both on the surface of the eye as a flexible, adherent wafer and as injected microencapsulates. This is particularly useful for the development of improved, next-generation therapies in ophthalmic indications in glaucoma, cataract surgery, etc. as well as the development of regimens to treat cancer and infections for other tissues and organs. This innovation can be considered transformational and can be the

platform engine for many future sustained release products.

Integral BioSystems seeks to develop a product pipeline utilizing this technology for a variety of indications including ophthalmic, urology, otic, intranasal, intra-uterine and rectal routes using new drug substances, as well as using approved drugs to pursue an aggressive 505b2 development strategy.

About Integral BioSystems
Since its formation in 2011, Integral BioSystems has established credibility in drug formulation, CMC consulting, analytical method development and methods qualification, as well as scale-up process engineering. Along with its strong presence as an ophthalmic product development CRO, the company also has expertise in other routes, including injectables, infusions, topical dermal gels/creams, and nanocrystals. Integral BioSystems provides expertise and know-how in developing both front-of-the-eye and back-of-the-eye products, offering complete development services in pre-formulation, including bioanalytical.

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