

Boston Area Drug Delivery Company Integral BioSystems Announces EPO Utility Patent Grant on OcuSurf™ Innovation

Specialty drug delivery company Integral BioSystems LLC has won a broad EPO utility patent allowance for its platform delivery innovation OcuSurf[™]

Integral BioSystems

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Boston-area hybrid CRO/innovation company <u>Integral BioSystems</u> has granted a patent allowance from the European Patent Office on one of its flagship inventions, OcuSurf[™], a novel, patented, differentiated and improved formulation approach for medications to treat disorders of the ocular surface and the anterior chamber of the eye. Products formulated in OcuSurf[™] are

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OcuSurf[™] maximizes drug product effectiveness while using a minimum amount of API to achieve your desired result″

Dr. Shikha Barman

highly bioavailable and tissue-permeating, due to its ability to rapidly absorb into tissue. OcuSurf[™] variants for other routes such as oral, dermal, rectal, and urology have been enabled with multiple small-molecule drugs. Due to the high tissue permeation enabled by OcuSurf[™], this innovation is an excellent 505b2 strategy for drug reformulation, either to bridge the revenue gap for patentexpired products or to offer a path to render insoluble, impermeable drugs bioavailable. Further, this patent is in

the process of being validated in the EU countries of Great Britain, Germany, France, Italy, and Spain.

The Details

A substantial number of ophthalmic drug products for disorders of the ocular surface are hydrophobic, or sparingly soluble in water, and formulated as suspensions. This results in less than 5% of each eye-drop actually being absorbed by the target tissue. Such formulations typically contain a high concentration of drug to achieve a therapeutic effect. OcuSurf[™] nanostructured emulsions are formulated into mucosa-penetrating, tissue absorbed nanoparticles, melting at body temperature to release dissolved drug at the requisite tissue site, allowing much less drug to be administered for equivalent or better therapeutic effect.

Integral BioSystems is developing an ophthalmic pipeline utilizing this technology. As a business strategy, Integral invites licensing-based collaborations for other potential applications in ophthalmic, dermal or other routes that can benefit from this technology.

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.

For companies seeking to develop a new product that is using a re-purposed drug, Integral offers its innovative delivery systems as licensable technologies to build value into prospective clients' drug products through a 505b2 regulatory strategy. For companies seeking product life cycle management, Integral can help them quickly ascertain if Integral's innovations can provide the desired improvements. With multiple billion dollar drug products going off-patent, this presents a cost effective way to develop an extended product life cycle with novel IP. In this manner, Integral will offer its insight and technological innovations in drug delivery to strategize and improve the customer's product portfolio. To this effect, Integral BioSystems has been a development partner for both innovative and generic companies.

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