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DRUG DELIVERY PLATFORM DRIVES NEW OPPORTUNITIES FOR CONTINUOUS-DELIVERY GLAUCOMA TREATMENT

Here, Harsh Patel, PhD, Senior Scientist, Cyonna Holmes, PhD, Global Ophthalmology Strategy Lead, and Brian Wilson, PhD, New Business Development Partner, all at Celanese, discuss how the company's VitalDose® EVA drug delivery platform can help reduce intraocular pressure by creating a desired therapeutic release profile.

Glaucoma is a prevalent disease among older populations and the global drug market is forecast to reach around US\$8.8 billion (£7.3 billion) in 2025 and around \$11 billion by 2030.¹ Market growth drivers include an increase in the ageing population and the emergence of new therapeutics. Although therapeutics exist to treat glaucoma, there remains an unmet need for improving treatment efficacy through increased patient adherence and drug bioavailability.

LIMITATIONS OF CURRENT THERAPEUTICS

Topical eye drops are a common first-line treatment in glaucoma. However, up to 60% of patients do not realise the full efficacy of their medications due to compliance and adherence issues, regimen complexity and, often, an initial asymptomatic presentation that results in improper dosing.² Bioavailability, drug elimination, rapid clearance and limited absorption at target sites can also diminish therapeutic efficacy.

Treatment goals focus on reduction of intraocular pressure (IOP) by 20%–50% to provide IOP control over the lifetime of this chronic condition.³ To address this challenge, newer treatments have emerged using novel mechanisms of action (MoA) and innovative drug delivery systems and

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devices. While novel MoAs focus on new IOP-lowering targets, most drug delivery systems for glaucoma aim to improve pressure management through sustained, longer-acting treatments. These patient-centric delivery systems have the potential to address common unmet needs and reduce the need for frequent dosing.

SUSTAINED RELEASE FOR GLAUCOMA THERAPEUTICS

Innovative, long-acting delivery options are being developed to address current treatment limitations and different routes of administration. Ocular inserts, intracameral depots and punctal plugs represent the wide range of potential routes for sustained delivery approaches. Therapeutic release via these routes varies in duration from three months to three years and provides continuous delivery for improved IOP management.

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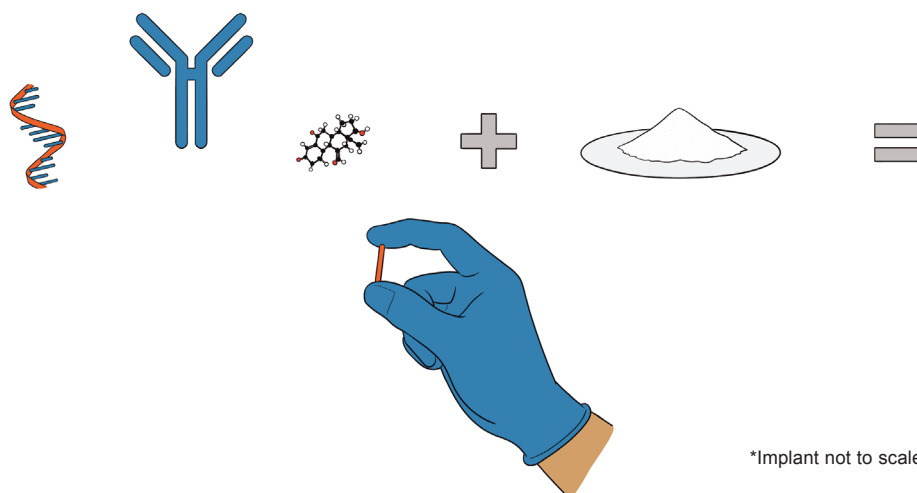
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“By combining these tubes, plates and shunts with a drug-eluting element, improved outcomes can be achieved with a combination device.”

Intracameral depots are an effective route of administration as demonstrated by Allergan’s (Dublin, Ireland) Durysta® (bimatoprost intracameral implant), the first long-acting glaucoma implant treatment to gain US FDA approval. Pipeline approaches being evaluated in trials include Ocular Therapeutix’s (MA, US) OTX-TIC (travoprost intracameral implant) and Glaukos’s (CA, US) iDose TR (travoprost intraocular implant) depots that both offer a sustained release of travoprost. These are localised dose forms placed near the site of action and are a route to consistent delivery and control of IOP.

PAIRING DRUG ELUTION WITH EXISTING GLAUCOMA DEVICES

Beyond the dose forms in development, there is an opportunity to pair ocular drug delivery with existing devices for IOP control using mechanical redirection of fluid flow. By combining these tubes, plates and shunts with a drug-eluting element, improved outcomes can be achieved with a combination device. Pairing these well-known and frequently used devices with a drug delivery mechanism would allow



*Implant not to scale

Figure 1: Sustained delivery of both small molecules and biopharmaceuticals can be achieved with VitalDose® EVA.

the mechanical and therapeutic modes of action to work in tandem. The addition of drug elution to these devices may also help reduce inflammation that is often associated with the implantation of these devices. A wide range of drugs, from antibiotics to anti-inflammatories to IOP-lowering agents, can be incorporated into these devices (Figure 1).

Since these devices are often made of durable polymers, non-erodible polymers are a natural choice in their redesign. The strength of durable polymers, such as Celanese’s VitalDose® EVA, in ocular-based drug delivery strategies include:

- High drug loading without compromising mechanical integrity or long-term release kinetics
- Drug-release profiles of 12 months or greater for small molecule therapeutics
- Minimal risk of drug molecule instability due to the absence of polymer degradants.

The size of most drainage devices offers the potential for a large loading of one or multiple drugs to be delivered over a period of time. These parts can be made via extrusion and moulding, approaches that are typically used in the fabrication of the original device parts. Films, rods and discs represent a small sampling of the form factors that are possible for the drug delivery component (Figure 2).

These delivery geometries can work to replace existing segments or entire parts within a medical device to allow for a dual-action approach. IOP-lowering medications can be released from VitalDose® EVA and the loading percentage can be tuned to achieve the desired release profile. Additionally, different form factors (film, rod, etc.) have demonstrated sustained release that further highlights adaptability to current medical devices.

ABOUT THE COMPANY

Celanese Corporation is a global chemical leader in the production of differentiated chemistry solutions and speciality materials used in most major industries and consumer applications. The company’s businesses use the full breadth of Celanese’s global chemistry, technology and commercial expertise to create value for its customers, employees, shareholders and the corporation. Celanese partners with its customers to address their most critical business needs and strives to make a positive impact on communities and the world through The Celanese Foundation. Based in Dallas (TX, US), Celanese employs over 13,000 employees worldwide and had 2021 net sales of \$8.5 billion.

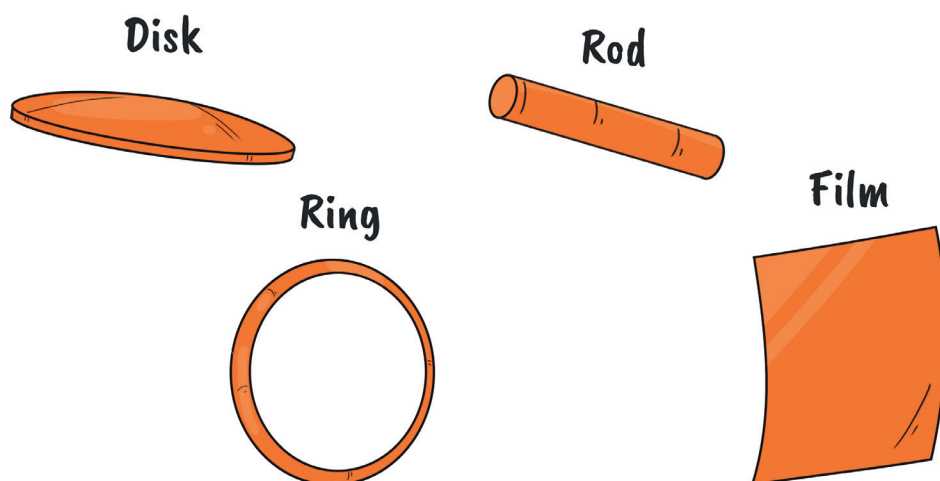


Figure 2: Form factor options provide flexibility in design.

For the pharmaceutical industry, Celanese offers the VitalDose® EVA drug delivery platform, providing controlled drug release through implants and inserts. Compared with traditional dose forms, the VitalDose® platform reduces treatment burden, addresses patient adherence issues and improves bioavailability. The company partners with clients to enable innovative drug delivery of small molecules, biologics and RNA within the desired release profile. With decades of experience in medical and pharmaceutical applications, Celanese seeks to improve product development and elevate patient care.

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ABOUT THE AUTHORS



Harsh Patel earned his PhD in Biomedical Engineering from the University of Alabama (Birmingham, AL, US) and his MS in Bioengineering from the University of Pittsburgh (Pittsburgh, PA, US). He has extensive technical experience in parenteral drug delivery across multiple polymers. At Celanese, Dr Patel serves as a Senior Scientist for Pharma & Medical and holds patents and has numerous published articles in peer-reviewed journals.



Cyonna Holmes earned her PhD in Biomedical Engineering from the University of Texas Southwestern Medical Center (Dallas, TX, US) and her BS in Bioengineering from Stanford University (Stanford, CA, US). At Celanese, Dr Holmes serves as Global Strategy Lead for Ophthalmology, Rare Diseases and RNA Therapeutics. She has experience in the areas of drug delivery, lifecycle management strategy, new product development and market entry strategy. She has published articles in peer-reviewed journals.



Brian Wilson earned his PhD in Biochemistry from the University of Notre Dame (IN, US). He has 11 years of API experience in the areas of formulation development, drug delivery and new product development. At Celanese, Dr Wilson serves as a new business development partner for the pharma and medical businesses. He holds patents and has numerous published articles in peer-reviewed journals.

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Versatile, innovative platform for ocular drug delivery

Our VitalDose® EVA technology is a drug delivery platform providing controlled release through implant and insert dosage forms. The VitalDose® EVA platform has proven biocompatibility and achieves >6 months release of **mAbs, peptides, small molecules, and fixed dose combination therapies**. We partner with you to enable innovation within your desired delivery profile.

The Celanese Development & Feasibility Lab offers the following support:

- Material selection
- Drug release testing
- Formulation and R&D
- Tech transfer prototype development

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