## AGO.highcostprescriptiondrugs@vermont.gov

## Re: Notice of a New Prescription Drug Pursuant to 18 V.S.A. § 4637(b)

Dear Office of the Vermont Attorney General,

Vericel Corporation is issuing this notice pursuant to 18 V.S.A. § 4637(b), which asks prescription drug manufacturers to provide the Office of the Attorney General (the "Office") written notice within three calendar days of releasing a drug in the commercial market whose wholesale acquisition cost ("WAC") exceeds the threshold set for a specialty drug under the Medicare Part D Program.

On January 16, 2023, Vericel Corporation introduced the following product to the market:

NDC	Description	WAC
69866-2005-03	NexoBrid (anacaulase-bcdb) For topical gel - 4.85 g anacaulase-bcdb in 5 g lyophilized powder. For Topical Use Only.	\$3,150.00

The WAC for the drug product(s) identified above exceeds the threshold set for a specialty drug under the Medicare Part D Program. Please note that the WAC-related information provided in this notice may be subject to change.

18 V.S.A. § 4637 does not currently define "release of the drug in the commercial market." Further, Vericel Corporation is not aware of any guidance issued by the Office or any Vermont regulation that defines "release of the drug in the commercial market" for the purpose of 18 V.S.A. § 4637.

In the event Vermont S. 92 and the laws it implements, including 18 V.S.A. § 4637, are found invalid, Vericel Corporation reserves all of its legal rights. In issuing this notice in an attempt to comply with 18 V.S.A. § 4637, Vericel Corporation does not waive any legal claims or legal rights related to potential constitutional defects with Vermont S. 92.

Sincerely,
Fangtin Yu
Senior Director of Market Access
Vericel Corporation