SAOL THERAPEUTICS

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Dear Members of the PDCD Community,

We are deeply grateful for the continued support and advocacy we have received from the PDCD community. Your partnership and commitment remain incredibly important to us.

As you know, in the FDA's Complete Response Letter (CRL) to Saol, the primary concern was whether the existing clinical studies were sufficient to support approval, and the FDA recommended at least one additional well-controlled study. The FDA did not raise concerns related to safety or manufacturing (CMC).

We subsequently held a Type A meeting with the FDA in December during which we provided additional analyses describing functional benefit, new survival analyses, mechanistic evidence that SL1009 (DCA) addresses the underlying enzyme deficiency in PDCD, and a well-established safety profile supported by more than 100 patient-years of exposure, including many patients treated for over four years.

As a result of these discussions, the FDA recommended a Type C meeting to further review the new survival analyses and discuss potential NDA resubmission without the need for an additional clinical trial. Our next steps include preparing for the Type C meeting, preparing for potential NDA resubmission, and continuing to support patient access to SL1009. While the FDA did not commit to accelerated timelines, we are hopeful they will review things more quickly. We are awaiting the meeting date from FDA, and are preparing to move quickly to the resubmission pending the meeting outcome.

While work remains, we are encouraged by this progress and remain hopeful that this represents a meaningful path forward for the program. Thank you again for your unwavering support. We are hopeful that 2026 will be our year—the sooner, the better for all of us.

With gratitude,

Dave Penake, CEO

Saol Therapeutics Inc.