July 1, 2026

Dear Members of the PDCD Community,

Today, we are proud to share that Saol Therapeutics has officially resubmitted our New Drug Application to the FDA for SL1009 (DCA) for the treatment of Pyruvate Dehydrogenase Complex Deficiency (PDCD).

This is an important milestone for the PDCD community and follows months of continued collaboration with the FDA, additional data analyses, and extraordinary advocacy efforts from families, physicians, researchers, and advocacy organizations. We are incredibly grateful for the support, partnership, and persistence this community has shown throughout the process.

Following constructive Type A and Type C meetings with the FDA, the Agency provided additional guidance to support the resubmission. Through these interactions, we confirmed that an additional clinical trial was not required before moving forward. With that clarity, we were able to proceed directly with resubmitting the application.

Over the past several months, we have continued to further strengthen the application through additional analyses and data supporting the potential benefit of SL1009 for individuals living with PDCD. We remain encouraged by our recent interactions with the FDA and are committed to advancing this process as quickly as possible.

We also want to acknowledge the incredible advocacy efforts from across the PDCD and mitochondrial disease communities. Your voices have helped raise awareness of the urgent unmet need facing families living with PDCD and the importance of flexibility in ultra-rare disease review pathways.

While the FDA review process continues, we remain focused on moving forward with urgency and transparency, and we are committed to keeping the community updated along the way.

Thank you for continuing to stand with us and with one another.

With gratitude,

Dave Penake, CEO
Saol Therapeutics Inc.