July 17, 2026

Dear Acting Director Mikhail and LCDR Reese,

We were gratified to hear that the FDA has accepted the resubmission of the Biologics License Application (BLA) for RP1 (vusolimogene oderparepvec) in combination with nivolumab for the treatment of advanced melanoma. We were further encouraged to hear of the advisory committee meeting on July 30, 2026, with the expeditious goal decision date of August 2, 2026.

Thank you.

As advocacy organizations who represent patients with melanoma, we know this reconsideration cannot come soon enough. As we've written previously, approximately half of patients with metastatic melanoma see a response to anti-PD1 or anti-CTLA-4 immunotherapies, and many are alive 10+ years after they first began treatment. But for the other half who don't see a response, or whose response is not durable, dismal survival statistics are their reality: The average lifespan for these patients is approximately one year.

When immunotherapy fails, the limited subsequent treatment options depend on variables such as patient health, geographic location, and BRAF mutation status. For many, there are no options.

There is an urgent and unmet need for safe and effective treatment options for patients who do not respond to immunotherapy—and there are thousands of these patients. Indeed, since last July, when the first complete response letter was issued for RP1+nivolumab, **over 8,000 people have died of melanoma in the U.S.,** a portion of whom **may have survived if RP1+nivolumab had been approved**.

Data from IGNYTE presented at the recent American Society of Clinical Oncology meeting showed promising results for your consideration: Nearly half of all treated patients in the study were alive at three years, including 83.5% of responders. Data also showed a median overall survival of 32.9 months and a manageable safety profile.

For all of these reasons, we applaud the resubmission and acceptance of the BLA, and the communication and collaboration between the FDA and the sponsoring company that led to it.

On a larger level, we also applaud the Breakthrough Therapy and Accelerated Approval programs, which are critical for diseases such as melanoma that rob so many Americans of healthy, productive years—or their lives altogether. The proactive and collaborative advice, communication, and guidance promised by FDA to sponsors as part of these programs are key to successful and rapid drug development, review and approval. These programs, when functioning properly, benefit patients immensely.

We have received hundreds of patient stories over the last year pleading for this treatment's approval, and we've shared some of those stories in previous letters. Here we'll close with one family's appeal: *RP1 is more than just a medication to us—it represents a potential lifeline. Please consider not just the data, but the very real human lives behind it. Patients who have exhausted all other treatment options deserve access to any promising treatment. We hope you will consider the impact this decision has on real people and real families.*

On behalf of the melanoma patient community, we urge you to approve RP1+nivolumab.

Sincerely,

aCUREINSIGHT.org ocular melanoma
AIM AT MELANOMA FOUNDATION
Claire Marie FOUNDATION
MAC MELANOMA ACTION COALITION
Melanoma Research Alliance
MRF Melanoma Research Foundation