Subject: Urgent Appeal for an Expanded Access / Compassionate Use Program in Europe for Daraxonrasib – A Personal and Community Plea

To:
The Executive Leadership Team & Early Access Committee
Revolution Medicines, Inc.

Dear Dr. Goldsmith, Members of the Board, and Clinical Leadership Team,

I am writing to you today in a threefold capacity: as President of the Fondazione Paola Marella ETS, as a representative of patient advocacy organizations, and, above all, as the husband of Paola Marella.

This journey is deeply personal to me and my family. In 2024, when clinical options were scarce and hope was essential, Paola had the privilege to participate in the Phase 1 clinical trial of your targeted therapy at the MD Anderson Cancer Center in Houston, under the dedicated care of Dr. David S. Hong. We experienced firsthand the extraordinary commitment behind your pioneering RAS-targeted science, and we witnessed how much trust, dignity, and hope patients invest in clinical innovation when facing this devastating disease.

Following the remarkable findings of the RASolute 302 trial—celebrated with a standing ovation at ASCO—and the recent approval of daraxonrasib by the US FDA for pre-treated metastatic pancreatic ductal adenocarcinoma, your therapy is recognized worldwide as the most significant clinical breakthrough for pancreatic cancer in decades.

Yet, scientific breakthroughs demand ethical responsibility and equitable access for those fighting against the clock.

In my role representing pancreatic cancer patient organizations and reinforcing the urgent appeal made by AIOM (Italian Association of Medical Oncology), I must bring to your immediate attention the distressing disparity European—and specifically Italian—patients currently face.

While US patients were granted early access prior to FDA approval through an expanded access program, European patients have no such route available. Despite EMA's orphan drug designation and open rolling review mechanisms, the regulatory submission in Europe has not yet materialized, leaving patients and oncologists in a state of helplessness.

The current global named-patient mechanism, which entails importing the drug at the US list price of approximately $39,000 per month, is ethically unsustainable. It creates severe inequalities, forcing families into devastating financial hardship during their most vulnerable moments.

Pancreatic cancer does not wait for international pricing negotiations or administrative delays. Time is the one luxury these patients do not have.

Having walked the corridors of MD Anderson alongside Paola, I understand viscerally what access to your research means to a patient and their family. On behalf of Italian patients, their families, and the oncology community fighting by their side, I urgently appeal to Revolution Medicines to:

Activate an Expanded Access / Compassionate Use Program (Uso Compassionevole) in Italy and throughout Europe, providing daraxonrasib free of charge prior to commercial availability, mirroring the compassion demonstrated in the United States;

Accelerate formal engagement and dossier submission with the EMA and national regulatory agencies (such as AIFA), ensuring that your life-prolonging therapy reaches all eligible patients without unnecessary delay.

Thank you for your transformative research, and thank you for listening to the voices of those who are waiting.

Respectfully yours,

Domenico Traversa

President, Fondazione Paola Marella ETS

Board Member representing Patient Organizations, AISP (Italian Association for the Study of the Pancreas)