

PROFILE // PharmaVoice 100

Legacy Leaders: Dr. Michael Hayden

The CEO at Prilenia has an unwavering dedication to address the needs of HD patients and their families.

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By PharmaVoice staff

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The clinical-stage company Prilenia is not Dr. Michael Hayden's first entrepreneurial venture — it's his fifth. Over the years, Hayden has contributed significantly to the life sciences industry through the development and launch of more than 35 new products, the identification of 10 disease-causing genes and, perhaps most importantly, helping Teva Pharmaceuticals win approval for Austedo (deutetrabenazine), the second drug ever to be authorized for Huntington's disease (HD) while serving as the company's president of global R&D and chief scientific officer.

While at Teva, Hayden came across another promising compound: pridopidine.

"He brought it into the R&D pipeline to better understand its mechanism and potential. Later in 2018, he founded Prilenia to further drive pridopidine's clinical development," one of his nominators says.

Today, pridopidine, Prilenia's lead asset, is in phase 3 trials for HD and is being evaluated in a phase 2/3 trial for ALS. In May 2022, a peer-reviewed article noted that the first-in-class agent showed a positive mechanism of action in "autophagy, a cellular process

critical to preserving neuronal health." In 2021, pridopidine received FDA fast track designation for HD and an orphan drug designation for ALS in addition to HD. One colleague notes that "pridopidine has become the most advanced treatment in development for maintaining function in HD, allowing for easy, athome administration for patients and their caregivers around the globe if approved. These milestones bring us steps closer to [Hayden's] vision to enable every patient with HD to have sustainable access to effective and safe treatments and universal access."

Hayden's unwavering passion to unravel the mystery of HD goes back to his days as a medical student in South Africa, where he first worked with patients and families to determine the disease's prevalence and impact. "It was these interactions that led him to dedicate his career to advancing research in HD and other neurodegenerative diseases. This devotion has been carried out throughout his career," says one of his nominators.

"I have seen firsthand how quickly HD compromises a person's ability to maintain their independence and keeps them from participating in activities of daily living. I've also walked alongside these families to know how long and difficult the journey can be through disability in the prime of their lives. What keeps me up is worrying that there will not be therapies in time to moderate the course of the disease," Hayden, a two-time PharmaVoice 100 honoree, says.

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Dr. Michael Hayden *CEO, founder, Prilenia*

Hayden's passion for the HD community and perseverance in the field have inspired many to join him along the journey.

"When I founded Prilenia, our core team was composed of people with whom I had previously worked. They took a risk to be a part of a startup with me, many taking on new responsibilities. I valued their commitment deeply and in turn, felt it was essential to support and mentor each of them. One of my greatest joys is to help my team grow individually and together," he says.

Hayden remains encouraged by the progress he and his team are making toward evolving and expanding the treatment paradigm for neurodegenerative conditions.

"My vision for Prilenia and our pipeline builds on my experience in the cardiovascular space at the beginning of my career — I want to make drugs for the brain possible, having learned from the development of statins," he says. "Initially, statins were only prescribed to people who had already experienced a heart attack in hopes of preventing another one. Yet, the real transformation in outcomes came when statins moved into primary prevention, being recommended to people who were at risk for their first heart attack. Developing medicines that can be used on the frontline of preventative care for people with inheritable neurodegenerative diseases is my ultimate vision for the future."