

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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**LUPIN LTD. and LUPIN PHARMACEUTICALS INC.**

**Petitioners,**

**v.**

**HORIZON THERAPEUTICS, LLC.**

**Patent Owner.**

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**DECLARATION OF KEITH VAUX, M.D.**

LUPIN EX. 1002

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I, Keith Vaux, M.D., declare and state as follows:

## **I. QUALIFICATIONS**

1. I am a medical doctor with specialty training in Pediatrics and Clinical Genetics. I am currently Professor and Clinical Chief of the Division of Medical Genetics in the Department of Medicine at UC San Diego. I also have an appointment as Professor of Neurosciences at UC San Diego, and I am a physician at Point Loma Pediatrics. Since 1994, I have regularly diagnosed and treated patients with urea cycle disorders (“UCD”), and continue to do so today. In treating UCD patients, I regularly prescribe nitrogen scavenging drugs and treat patients who are maintained on therapy with nitrogen scavenging drugs.

2. I received a B.A. in History, Philosophy and Social Studies of Science and Medicine from the University of Chicago in 1987, and an M.D. from the University of Chicago in 1994. I have an unrestricted license to practice medicine in the State of California.

3. After medical school, I completed a three year residency in pediatrics, including a year as Chief Resident, from 1994-1997. The recognition, immediate and long-term management, and consideration of the long-term prognosis, of Urea Cycle Defects is a core competency for training and board certification in Pediatrics. Following two years of isolated clinical pediatric practice and critical care transport in Guam and two years as a practicing

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pediatrician and faculty member at the Naval Medical Center, I completed a three-year fellowship in dysmorphology and medical genetics with an additional certificate in teratology (environmentally induced birth defects) at UC San Diego from 2001 to 2004. I am Board Certified by the American Board of Pediatrics (received in 1997 and recertified in 2007 and 2015), am a Fellow of the American Academy of Pediatrics and serve on the AAP National Council on Children with Disabilities and Society on Genetics and Birth Defects. I am a member of the California Department of Public Health, Genetic Diseases Screening Program Biobank Committee which address policy issues surrounding metabolic screening in newborns.

4. I teach Medical Students, Medical and Pediatric Residents and Specialty Fellows in Genetics, Complex Care Pediatrics and Metabolic Diseases. I have published in peer-reviewed journals on metabolic disorders. I regularly speak at national and international conferences on a variety of genetic, metabolic and genomic medicine topics.

5. A copy of my curriculum vitae, which sets forth my education and experience in further detail, is provided herewith as Exhibit 1023.

6. I have been engaged as an expert on behalf of Petitioners Lupin, Ltd. and Lupin Pharmaceuticals, Inc. I am being compensated for my time at my

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