

## **Bylvay™ (odevixibat) EMA Approval FAQ for PAGs**

### **1. What is Bylvay and what is it approved to treat?**

- Bylvay (odevixibat) has been approved by the European Commission (EC) for the treatment of progressive familial intrahepatic cholestasis (PFIC).
- It is a once-daily, non-systemic ileal bile acid transport inhibitor (IBATi). It can be taken as a once-daily capsule, or it can also be opened and sprinkled onto soft food to help with adherence for young children. It does not require refrigeration and is easily administered.

### **2. What is PFIC?**

- Progressive familial intrahepatic cholestasis, or PFIC, is a rare and devastating disorder affecting young children that causes progressive, life-threatening liver disease in which children are unable to drain bile from the liver.
- In many cases, PFIC leads to cirrhosis and liver failure within the first 10 years of life.
- The most prominent and problematic ongoing manifestation of PFIC is pruritus, or intense itching, which often results in a severely diminished quality of life.
- Up until now, there have been no approved drugs for PFIC, only surgical options that include biliary diversion surgery (BDS) and liver transplantation, and without them most PFIC patients do not survive past the age of 30.

### **3. How does the approval of Bylvay change the standard of care for patients with PFIC?**

- Before Bylvay, there were no medicines approved for PFIC—only invasive surgical options, including a procedure known as biliary diversion surgery (BDS) and liver transplantation.
- Under the care and recommendation by their physician, patients may now be able to take an oral once-daily medication.

### **4. How can patients get Bylvay? When will it launch in Europe?**

- Bylvay has been approved by the EC. In the second half of 2021, we will work with individual countries to finalize access and launch, with Germany as the first planned launch following price listing.
- In the meantime, for updates and more information, visit [albareopharma.com](http://albareopharma.com), [childliverdisease.org](http://childliverdisease.org) or [pfic.org](http://pfic.org).

### **5. Where can I get more information? What should I do next?**

- Talk to your doctor to determine if you should be treated with Bylvay.
- Learn more about Bylvay at [www.albareopharma.com/programs/bylvay](http://www.albareopharma.com/programs/bylvay)
- Join an educational patient town hall event, date TBD but more to come soon.