



**EU-PFF**  
EUROPEAN PULMONARY FIBROSIS FEDERATION



# **Pulmonary Fibrosis Community Advisory Board (PF-CAB)**

**28th March 2023**



## WHAT IS A COMMUNITY ADVISORY BOARD? (CAB)

A Community Advisory Board (CAB) is a working group of patient advocates formed to monitor pharmaceutical or non-pharmaceutical developments for a given disease. CABs interact and cooperate with key stakeholders, over the long-term, including: pharmaceutical companies, regulators, and the scientific community.



## THE PF - CAB

The European Pulmonary Fibrosis Federation (EU-PFF) has set up a **Pulmonary Fibrosis Community Advisory Board (PF-CAB)** as a working group of the EU-PFF. It comprises a panel of leading European patient advocates who can also call on other international experts. PF-CAB members work together to address issues of strategic importance to the PF community. They advocate for the best possible research and improved and equal access to innovative treatments and care for PF patients. PF-CAB monitors pharmaceutical developments, research and other developments in PF through, long-term cooperation and continued dialogue with pharmaceutical partners, regulators, medical experts, and the scientific PF-community.

**This report covers the first PF-CAB meeting, which was organised with Chiesi Pharmaceuticals**

## PARTICIPANTS

- PF -CAB Members
- Chiesi Farmaceutici (Chiesi) Representatives

Meeting Chaired by:  
Steve Jones, EU-PFF President

Meeting moderated by:  
Jan Geissler, Patvocates

Minutes prepared by:  
Stefanie Bockwinkel, Medical Writer



## SUMMARY

Community Advisory Boards provide an opportunity to build a meaningful relationship between pharmaceutical companies and the patient community to overcome the challenges and needs associated with pulmonary fibrosis (PF).

The **main objectives of the CAB meeting with Chiesi:**

1. To discuss **various aspects around the drug development pipeline of PF drugs**
2. To discuss **involvement of the PF community in Chiesi's research & development (R&D)**
3. To get **patient perspective on future Chiesi IPF clinical trials**

Both sides agreed to set up regular alignment calls on patient involvement in R&D and to further liaise on affiliate level, if possible. Other topics to be discussed in separate meetings outside the CAB meeting, include: developments of other forms of administration and decentralization of clinical trials and PROs.

All parties appreciated the open dialogue and collaboration and expressed their commitment to continue discussions during regular touch points and in smaller group discussions.

The meeting was held under confidentiality terms to allow for an open and frank discussion.



## CHIESI'S DRUG DEVELOPMENT PIPELINE OF PF DRUGS

A broad overview of the compounds currently in development was given, with the objective to get patient insights on:

- Research priorities
- Outcomes expected
- Route of administration

## *PATIENT INVOLVEMENT PROCESS*

### **REGULAR ALIGNMENTS ON PATIENT INVOLVEMENT:**

- Chiesi and EU-PFF to set up regular calls to further align patient involvement plan of Chiesi and their clinical development plans in order to make the programs as patient centric as possible.
- EU-PFF to help set up a small group of patient advocates to consult Chiesi along the whole process of clinical development.

### **PATIENT INVOLVEMENT ROADMAP:**

- EU-PFF to help select patients/carers/advocates and to define who they could be involved at which stages of Chiesi's development.

## CLINICAL TRIAL DESIGN

### CHOICE OF PRO'S:

- PF-CAB / Chiesi to exchange documents and compare patient reported outcomes (PROs) and then make suggestions based on relevance of domains for IPF.

### REGULATORY DISCUSSIONS ABOUT FUTURE TRIALS:

- Chiesi to explore involvement of PF patient advocates in interactions with Regulatory bodies on future Chiesi studies.

### DECENTRALISED TRIALS:

- Chiesi to follow-up with EU-PFF on decentralising elements of the studies to make trials more accessible.

## CHIESI'S ENGAGEMENT IN IDIOPATHIC PULMONARY FIBROSIS (IPF)

Chiesi is an international biopharmaceutical group with strong local community roots. It is a research-focused company that develops and markets innovative therapeutic solutions in respiratory health, rare diseases and special care, counting on 7 R&D centres (Italy, Canada, China, France, United states, UK and Sweden).

Chiesi's mission is to improve people's quality of life. For this reason, it acts responsibly towards patients, the environment, and the communities in which it operates, combining its commitment to results and integrity both for society and the planet.

Further information are available at <https://www.chiesi.com/en/home>

Chiesi is dedicated to addressing the challenges posed by IPF and other progressive fibrotic disorders in the lungs such as Progressive Pulmonary Fibrosis (PPF). Guided by a patient-centric approach, the company strives to pioneer solutions that make a meaningful impact on the lives of individuals grappling with these complex respiratory conditions. Chiesi pipeline includes three strategic targets focused on IPF and PPF, with one currently advancing through the clinical phase in patients.

## PF-CAB EXPECTATIONS ON PATIENT ENGAGEMENT IN GENERAL

### PF-CAB expectations on patient engagement in general:

- To know the roadmap for study programs;
- Chiesi will explore how to work with patients to agree method of selection, design, monitoring and impact analysis (KPIs);
- Chiesi will further work on patient's engagement through more systematically alignments on access strategies at European level and possibly at national level

## RECOMMENDATIONS TO IMPROVE THE PATIENT JOURNEY IN IPF

### Chiesi's perspective to improve patient journey in IPF:

- Despite recent advances, there are still gaps and medical needs present in IPF.
- The diagnosis of IPF is challenging and requires specialised multidisciplinary clinical expertise.
- Symptoms of IPF can easily be confused with other respiratory diseases or cardiological diseases.
- For the above mentioned reasons, the diagnosis is often delayed.
- According to the outputs of a survey conducted in 2020 in 14 countries with the involvement of the EU-PFF (capturing both healthcare professional- HCPs- and patient perspective), some recommendations may be taken into account to improve the IPF patient journey:
  - Raise awareness of PF/IPF
  - Increase access to interstitial lung disease (ILD) specialists
  - Fewer restrictions for pharmaceutical treatment
  - Greater focus on symptom-centred management
  - Information and support throughout the disease course

### Feedback/comments from PF-CAB:

- EU-PF CAB agreed on the recommendations and suggested working with Chiesi to raise awareness on PF/IPF.
- EU-PF CAB saw the time to diagnosis as the main problem for IPF patients.
- EU-PF CAB also emphasised the important role of specialised nurses for IPF (interacting with patients, assisting patients, helping in case of side effects etc.).

## INVOLVEMENT OF PF PATIENT COMMUNITY IN CHIESI'S R&D

### **Strategic principles of patient engagement at Chiesi:**

- Chiesi is constantly working on elevating its overall patient centric approach, through a journey towards direct engagement with of patients and co-creation with the patient community.
- In particular, Chiesi is strengthening strategic partnerships with the patient community through Patient Groups in order to gathering insights, needs, pain points and gaps along the entire patient journey, and at the same time co-design and co-create solutions that are able to improve patients health outcomes.
- Moreover Chiesi promoting this continuous dialogue with relevant stakeholders in the healthcare ecosystem wants to sustainably improve healthcare in a way that meets the expressed needs and preferences of patients.

### **Patient activities for IPF at Chiesi:**

- Chiesi believes in strong networks with key stakeholders in IPF.
- Chiesi's recent patient activities include sponsorship of IPF awareness & education activities, such as EU-PFF Patient Summits and webinars, a support group's nurse training and collaboration with local patient advocacy groups (PAGs) working towards equal access to information.

### **With patients into clinical development:**

- Chiesi aims to establish relationships that are built on trust and mutual respect in order to implement the voice of patients into the clinical development, whenever possible.
- Chiesi considers the perspective of patients as unique in nature and as a specialist knowledge that complements insights from other stakeholders (e.g. Healthcare professionals (HCPs), industry, regulators, Health Technology Assessment (HTA) bodies etc.).
- Chiesi shared examples of regulatory bodies in EU and the US that recognize a formal role of patient engagement in R&D. The company aims to meet these goals through co-development with patients.
- Chiesi's Side-By-Side with Patients initiative was launched with the aim to develop and consolidate the collaboration with patient experts into the clinical development process.
- Chiesi shared the company's DANCE (DigitAl iNnovation for patient Centric hEalth) scope and objective to enhance the clinical trial journey merging the patient perspective with modern technology.

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