**Introduction**

- Pancreatic cancer is a **fatal disease** and there exists a high **unmet medicinal need**.
- Pancreatic cancer is a **difficult disease to treat** and many clinical trials fail (Thota R et al. Pancreas. 2017).
- Throughout the years, numerous applications for orphan medicinal product (OMP) designation were received by the Committee for Orphan Medicinal Products (COMP).

**Research aim**

- To **provide more detail on OMP** for pancreatic cancer and identify if marketing authorisation applications can be expected in the near future.

**Information sources**

- Internal and publicly available data from the COMP database were used in this study.
- Information was collected from summary reports, protocol assistance letters, annual reports and public summaries.

**Results (1)**

- A total of **80 applications** were submitted to the COMP between 2000 and 2019 and **52 medicinal products** were granted OMP designation.
- At the time of submission, **18 OMPs were in the non-clinical stage** of development and **34 OMPs were in the clinical stage** of development (Figure 1).

**Results (2)**

- MoAs explored included, but were not limited to, stimulating an immune response \(n=12\), blocking signaling pathways \(n=8\), Inhibiting DNA synthesis \(n=5\), infecting tumour cells and replication therein \(n=5\).
- From the 52 OMPs, **1 OMP obtained a marketing authorisation** and **17 OMPs were still in development** according to the latest annual report.

**Conclusions**

- There is a **high interest from drug developers** as seen from the number of applications.
- At time of application 2/3 of the OMPs were already in the **clinical stage** of development.
- **Various MoAs** are being investigated.
- Drug development is **difficult** with a high failure rate, and to date only 1 OMP received MA.
- For several OMPs development is still ongoing and sponsors still plan to submit for MA in the near future.

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**Figure 1.** Stage of development at time of designation. (a) Highest ranked study(ies) conducted in the non-clinical stage of development. (b) Highest ranked study(ies) in the OMPs in the clinical stage of development.

**Figure 2.** Current status of the 52 OMPs for pancreatic cancer.

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