



Memorandum of Understanding

between

Takeda Pharma A/S

Delta Park 45, 2665 Vallensbæk Strand Denmark

&

Sjældne Diagnoser

Blekinge Boulevard 2
2630 Taastrup, Denmark

Memorandum of understanding regarding the
Nordic Rare Disease Summit
(12-13 April, 2021)

(Replacing the previous version of
Memorandum of Understanding
entered into in November 2019
between Takeda and Sjældne Diagnoser)



1. Partners

The below undersigned:

Takeda Pharma A/S

Delta Park 45
2665 Vallensbæk Strand, Denmark
(here after referred to as "Takeda")

and

Sjældne Diagnoser

Blekinge Boulevard 2
2630 Taastrup, Denmark
(here after referred to as "Sjældne Diagnoser")

have entered the following non-binding Memorandum of Understanding ("MoU"). For the avoidance of doubt, this MoU replaces the latest version of the Memorandum of Understanding entered into in November 2019 between Takeda and Sjældne Diagnoser.

This MoU sets out to reflect the Parties discussions in relation to, and outline how Sjældne Diagnoser, at their sole discretion, will co-host, work together with and, provide input to a meeting Takeda is planning ("Nordic Rare Disease Summit").

2. Rare Disease Summit

In order to raise awareness of rare diseases throughout the Nordic countries, Takeda is organising and funding the Rare Disease Summit, to take place virtually on 12-13 April 2021 with the possibility of satellite face-to-face meetings in the Nordic capitals and Brussels, Belgium, pending the Covid-19 situation. The event is organised as a Takeda owned Non-Promotional meeting (TOME).

The aim of the Rare Disease Summit is threefold:

1. To shape rare diseases policies to improve access and services by demonstrating the need for new innovative approaches at national level
2. To share existing good practice examples (diagnosis and quality of care/treatment/services) and foster consensus around solutions and approaches that should be broadly implemented
3. To investigate how empowerment can be used as a resource for patients and their relatives to secure better outcome of diagnostic and care

These aims will be pursued through:

1. The Rare Disease Summit's execution (programme, themes, speakers)
2. The launch and presentation of relevant evidence at the Rare Disease Summit, including a new study applying the ORPH-VAL pricing & reimbursement principles on the Nordic countries
3. The strengthening of relations between key stakeholders and follow-up corporation for improvement of national rare disease plans
4. Securing a lasting legacy of the Rare Disease Summit through a message which unites all stakeholders in an outcome document: 'The Nordic Roadmap for Rare Disease'

For the planning of the Rare Disease Summit, the Parties have had multiple discussions and Sjældne Diagnoser will continue to work together with Takeda and provide input to the planning and execution of the Summit, as per this MoU. As further outlined below, Sjældne Diagnoser will also act as co-host of the Rare Disease Summit.

3. National and international codes, laws and regulations

Both parties stress that it is a precondition for any activities contemplated in this MoU that all activities comply with LIF's, ENLI's and EFPIA's Code of Practice on Relationships between The Pharmaceutical Industry and Patient Organisations as well as national and EU regulations governing interactions between the pharmaceutical industry and patient organisations. The relation between both parties should also be fully compliant with Sjældne Diagnoser's ethical guidelines for the corporation with the pharmaceutical industry.

4. Scope

The Rare Disease Summit is a Nordic event gathering participants representing governments, national and regional institutions, international organisations, patient associations, health care professionals, academics, foundations, NGOs and media. The main part of the participants should come from countries within the region, but representatives from European and international organisations and institutions may also be invited.

The Parties have organised the recording of a video presentation by HRH Crown Princess Mary, opening the summit in her capacity as patron of Sjældne Diagnoser.

5. Roles and Responsibilities

Organiser and funder

Takeda is the host, organizer and funder of the Rare Disease Summit and overall responsible for the agenda of the Takeda owned Non-Promotional meeting (TOME)

Takeda will:

1. invite at least one Takeda keynote speaker/panellist to the Rare Disease Summit
2. have at least 10 Takeda delegates present at the Rare Disease Summit
3. identify delegates and invite these to the Rare Disease Summit
4. commission and facilitate the development of the ORPH-VAL Nordic publication by Dolon
5. be responsible for organizing the Rare Disease Summit:
 - a. facilitate and manage contacts with relevant external stakeholders
 - b. facilitate communication between hosts, endorsers and other stakeholders
 - c. commission a full-time employee to facilitate the organization of the conference and fund logistics management as well as public affairs consultancy
 - d. support the Rare Disease Summit in external communications before, during and after the Rare Disease Summit
6. appoint one person to liaise with the co-host

Co-host

Sjældne Diagnoser will co-host, work together with and provide input to the set up and design of the Rare Disease Summit. As such, Sjældne Diagnoser will:

1. in co-operation with Takeda provide input on:
 - objectives and themes of the Rare Disease Summit;
 - programme and keynote speakers;
 - list of invitees and format for distributing invitations;
 - list of endorsers;
 - communication strategy; and
 - dissemination strategy on the ORPH-VAL Nordic publication.
2. allow Takeda to use their name and logo in all communication materials related to the Rare Disease Summit.
3. contribute with at least one speaker/panelist from their organisation to the Rare Disease Summit, subject to specific contract(s).
4. suggest delegates to be invited to the Rare Disease Summit.
5. be part of the strategy making regarding communications before, under, and after the Rare Disease Summit.



6. be the co-signatories on external communications of the Rare Disease Summit.
7. be part of reviewing the ORPH-VAL Nordic publication along with Takeda.

Additionally, Sjældne Diagnoser may:

1. suggest participants representing patients living with a rare disease to be invited to the Rare Disease Summit.
2. facilitate on-going relations with Danish authorities.

Partners

Takeda will invite other selected parties as "partners" of the Rare Disease Summit, such as, EURORDIS, a non-governmental patient-driven alliance of patient organizations representing 932 rare disease patient organizations in 73 countries and SBONN (Sällsynta Brukerorganisationers Nordiska Nätverk), a network of six umbrella organizations for rare diseases in five Nordic countries and The Danish Association of the Pharmaceutical Industry (Lif).

As partners of the Summit EURORDIS, SBONN and The Danish Association of the Pharmaceutical Industry (Lif) will contribute to the Summit in the following way:

1. Provide input to final shaping of agenda of the summit and drafting of the Copenhagen Declaration.
2. Take part in selected follow-up activities to leverage the commitments after the Rare Disease Summit.
3. Allow the usage of their name and logo on branded materials in relation to the Rare Disease Summit ("Partners: EURORDIS, SBONN and The Danish Association of the Pharmaceutical Industry (Lif)").

In addition, EURORDIS will contribute with two speakers to share findings from a comprehensive publication on patient empowerment and to present the European recommendations for improving overall access to medicines for patients with rare disease.

The Danish Association of the Pharmaceutical Industry (Lif) will contribute with the CEO as a member of the panel discussing recommendations for Nordic pricing and reimbursement systems and how patients access to innovation can be improved. Further, Lif will involve the associations' Rare Disease Committee in validating an analysis of how the Nordic countries align with nine European ORPH-VAL principles for assessment of medicines for rare diseases.

Endorsers

Takeda will also invite "endorsers" to support the Rare Disease Summit such as, EFPIA (European Federation of Pharmaceutical Industries and Associations), EUCOPE (European Confederation of Pharmaceutical Entrepreneurs), Danmarks Bløderforening and Innovative Smaller Life science companies (IML).

Endorsers will:

1. enter into a dialogue with Takeda and Sjældne Diagnoser on the Rare Disease Summit (without including any temporal or other commitments in this regard);
2. allow the usage of their name and logo on branded materials in relation to the Rare Disease Summit, including the ORPH-VAL Nordic publication and the Copenhagen Declaration;
3. be encouraged to invite two relevant delegates to the Rare Disease Summit; and
4. take part in selected follow-up activities to leverage the commitments after the Rare Disease Summit



6. Signatures

Sjældne Diagnoser
Copenhagen,

Takeda Pharma A/S
Copenhagen,

Birthe Byskov Holm
Formand
Sjældne Diagnoser

Patrik Forsell
General Manager
Takeda Pharma A/S

Takeda Pharma A/S

27 NOV. 2020

Takeda Pharma A/S

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