
Active Biotech

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Active Biotech in Brief

Clear focus on specialist disease areas

- **Large** unmet medical need and value potential
  - Hematological cancers (clinical Ph I/IIa study ongoing)
  - Inflammatory eye disorders (clinical Ph I study)
  - Selected solid tumors – partnered project (ongoing clinical Ph I & II studies)
- **Opportunity** to leverage prior generated data to accelerate development
- **Multiple** near-term clinical milestones

Experienced leadership

- **Senior** organization and **Board** with complementary skills
- **Broad** international network of KOLs and experts

Finance & Corporate

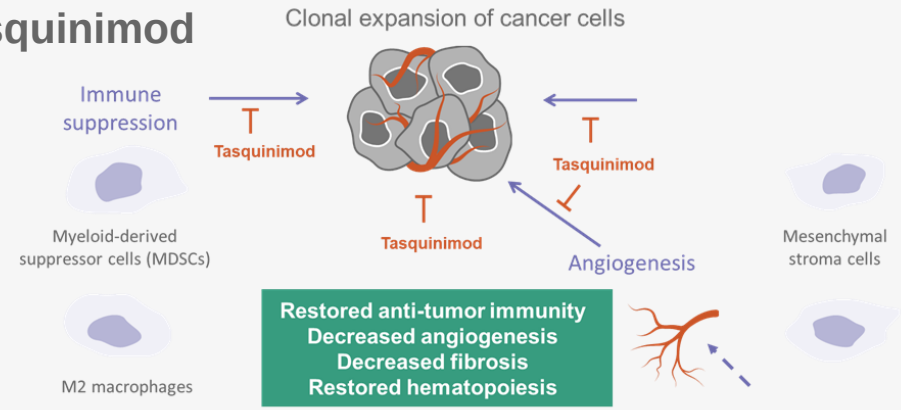
- Listed on Nasdaq Stockholm (ticker: ACTI)
  - Market cap SEK 240 M, USD 22,6 M*
- Strong shareholder base, incl MGA Holding, Sjuenda Holding, AP3 and AP4
- Founded in 1998 as spin-off from Pharmacia, based in Lund, Sweden

* As of 6 Feb 2024

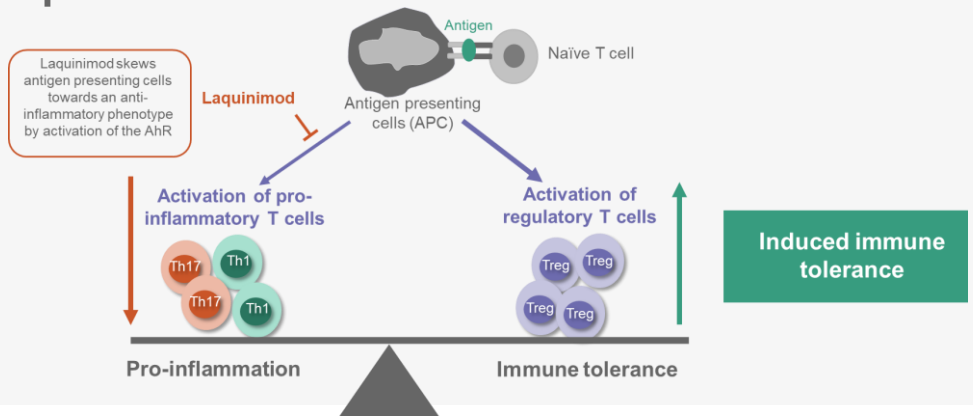
Immunomodulation to Treat Cancer and Inflammation

Small molecules
- myeloid cell modulation

Tasquinimod

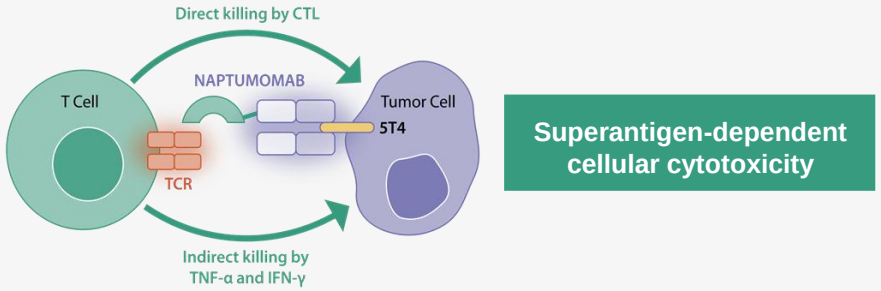


Laquinimod



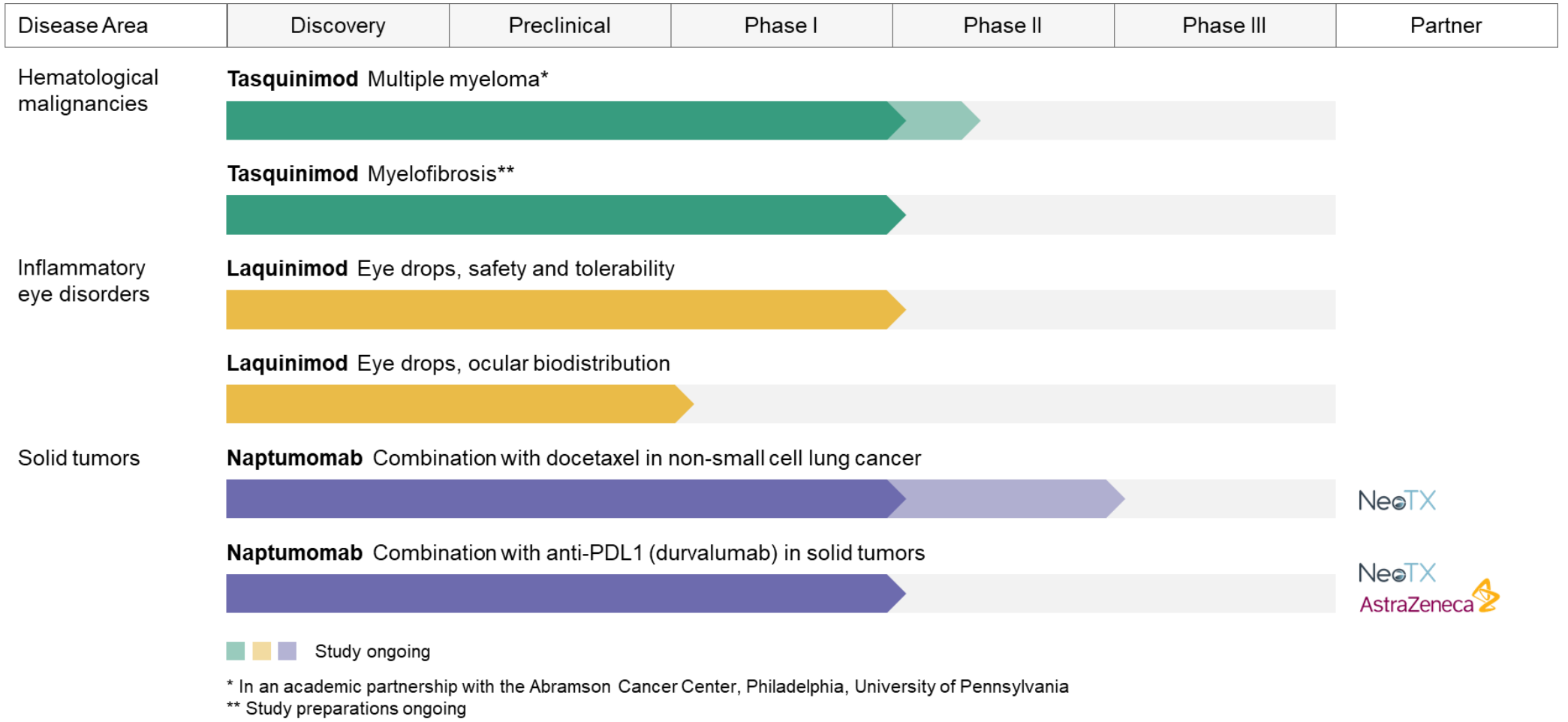
Antibody based immunotherapy
- tumor targeting superantigen

Naptumomab



Abbrev:, MDSC – Myeloid derived suppressor cell; HDAC4 – Histone deacetylase; APC-Antigen Presenting Cell, T reg-Regulatory T cell, Th 1-T helper cell 1, Th17-T helper cell 17; CTL – Cytotoxic T lymphocyte; TNF – Tumor necrosis factor; IFN – interferon; TCR – T cell receptor

Valuable Clinical Pipeline in Specialist Indications



Key Collaborations with Academic Partners

Tasquinimod

Multiple myeloma

- Yulia Nefedova, M.D., Ph.D. Associate Professor, Immunology, Microenvironment & Metastasis Program, The Wistar Institute Cancer Center, Philadelphia, US
- Kim De Veirman, PhD, Brussels Health Campus VUB, Brussels

Myelofibrosis

- Rebekka K Schneider, M.D., PhD. Department of Hematology, Erasmus MC, Rotterdam
- Kapil Bhalla, M.D., F.A.C.P.,Professor, Department of Leukemia, Division of Cancer Medicine, MD Anderson University of Texas, MD Anderson Cancer Center, USA

Myelodysplastic syndrome

- Manja Wobus, PhD, Universitätsklinikum Carl Gustav Carus an der Technischen Universität Dresden
- Katja Sockel, M.D., PhD. Hemato-/Oncological Outpatient Clinic, University Hospital Dresden

Laquinimod

- Rachel Caspi PhD, Associate Professor, Chief of the Laboratory of Immunology, National Eye Institute, NIH, Bethesta (MD), USA

Tasquinimod: New Type of Treatment for Hematological Malignances with Unmet Medical Need

Active Biotech

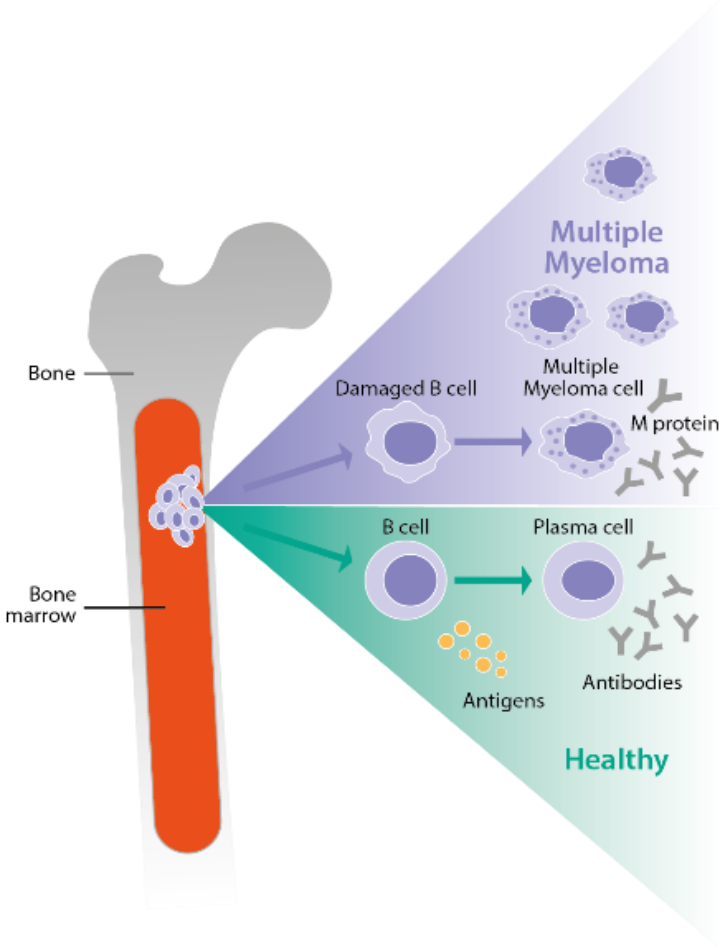
Ongoing study	Core focus	High value opportunity
Multiple myeloma (MM)	**Myelofibrosis (MF)**	**Myelodysplastic syndrome (MDS)**
Blocking of the tumor-supportive bone marrow microenvironment to complement existing treatments ➢ Clinical Ph Ib/IIa combination with IRd ongoing in US	Disease modifying by targeting the bone marrow microenvironment ➢ Clinical PoC studies planned to start in 2024	Restoration of hematopoiesis by targeting the bone marrow microenvironment ➢ Preclinical PoC established*

- ✓ Oral treatment with novel mechanism of action
- ✓ PFS benefit in advanced oncology patients and well-known safety
- ✓ Opportunity to leverage established regulatory package of preclinical, clinical safety (> 650 pts-years of exposure) and full commercial scale CMC documentation
- ✓ US orphan drug designation granted in multiple myeloma and myelofibrosis & exclusivity by patents and patent applications to at least 2043

Abbrev: PFS – Progression Free Survival; CMC - Chemistry, Manufacturing and Controls, IRd – Ixazomib Revlimide dexamethazone

* Wobus et al. Posters presented at ASH 2021 and 2022

Multiple Myeloma: An Incurable Blood Cancer

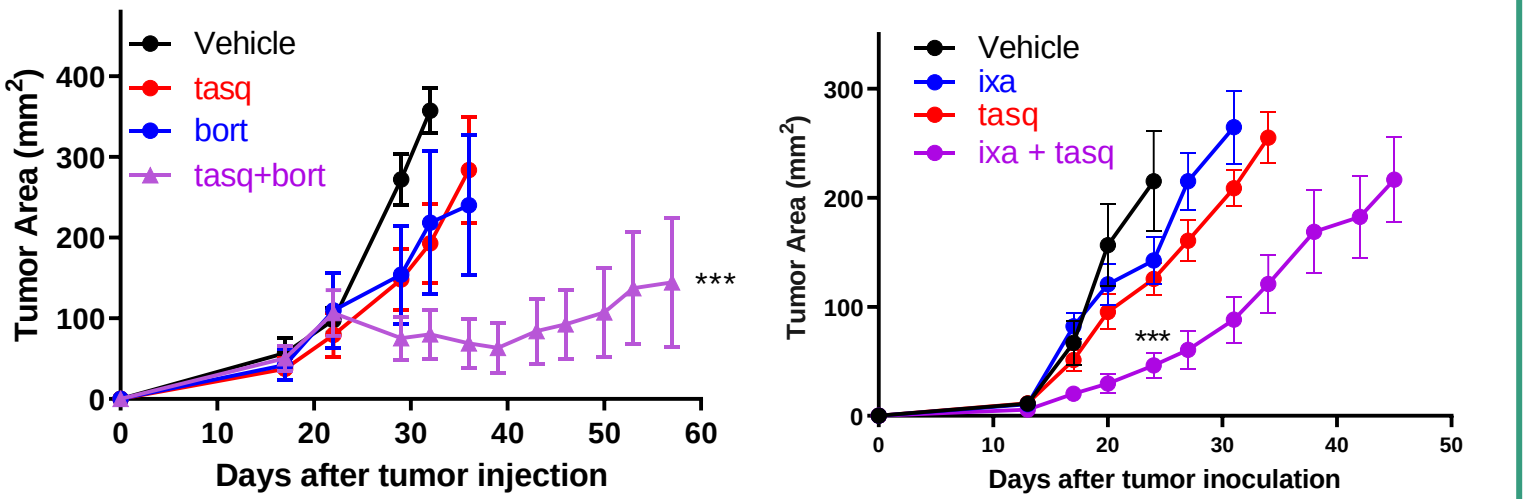


- Multiple myeloma develops in the bone marrow
- Uncontrollable growth of plasma cells
- Formation of new blood cells prevented
- Leads to bone pain, fractures, anemia and other severe complications, e g renal failure and infections
- Survival has increased due to more treatment options available. Median survival is now estimated to 8-10 years from diagnosis
- Patients relapse and eventually die due to resistance to current treatments

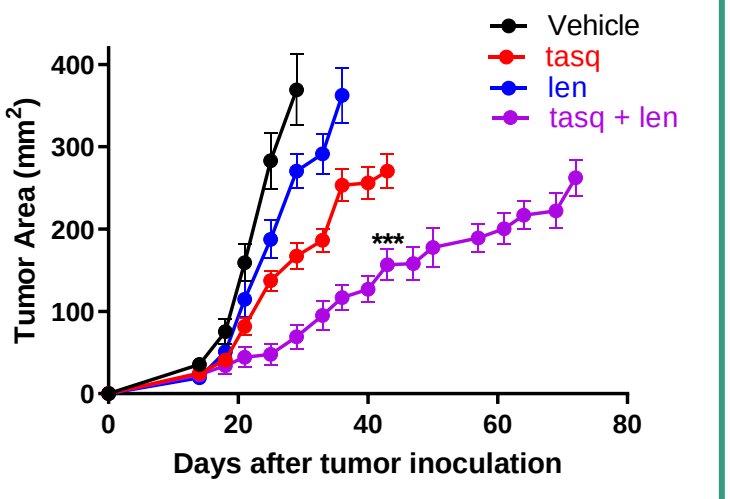
The medical need remains high

Tasquinimod: Synergy in Combination with Anti-Myeloma Treatments

Tasquinimod in combination with proteasome inhibitors (PIs)



Tasquinimod in combination with an immunomodulatory drug (IMiD)



Multiple myeloma tumors were established by subcutaneous injection of human H929 cells into NSG mice. Mice were treated with tasquinimod, bortezomib, ixazomib or lenalidomide.

Abbrev: tasq – tasquinimod; ixa – ixazomib; len – lenalidomide
Source: Lin et al., Poster presented at the Virtual Edition of the 25th European Hematology Association (EHA) Annual Congress Meeting, 2020

Ongoing Ph Ib/IIa Study in Multiple Myeloma

Patients
MM relapsed or refractory after ≥1 line of anti-MM therapy and refractory or intolerant to lenalidomide, pomalidomide, bortezomib, carfilzomib, and an anti-CD38 mAb

Part A1 (N=10)
Dose escalation of tasquinimod
Completed

Part B1 (N=6)
Dose escalation of tasquinimod in combination with standard oral regimen
Completed

Part B2 (N=up to 12)
Expansion at MTD of combination
Ongoing

Patients
MM relapsed or refractory after ≥1 line of anti-MM therapy and refractory to most recent PI/IMiD-combination

Primary endpoint
Safety & tolerability, (MTD)

Key secondary endpoint
Preliminary efficacy by clinical response (ORR)

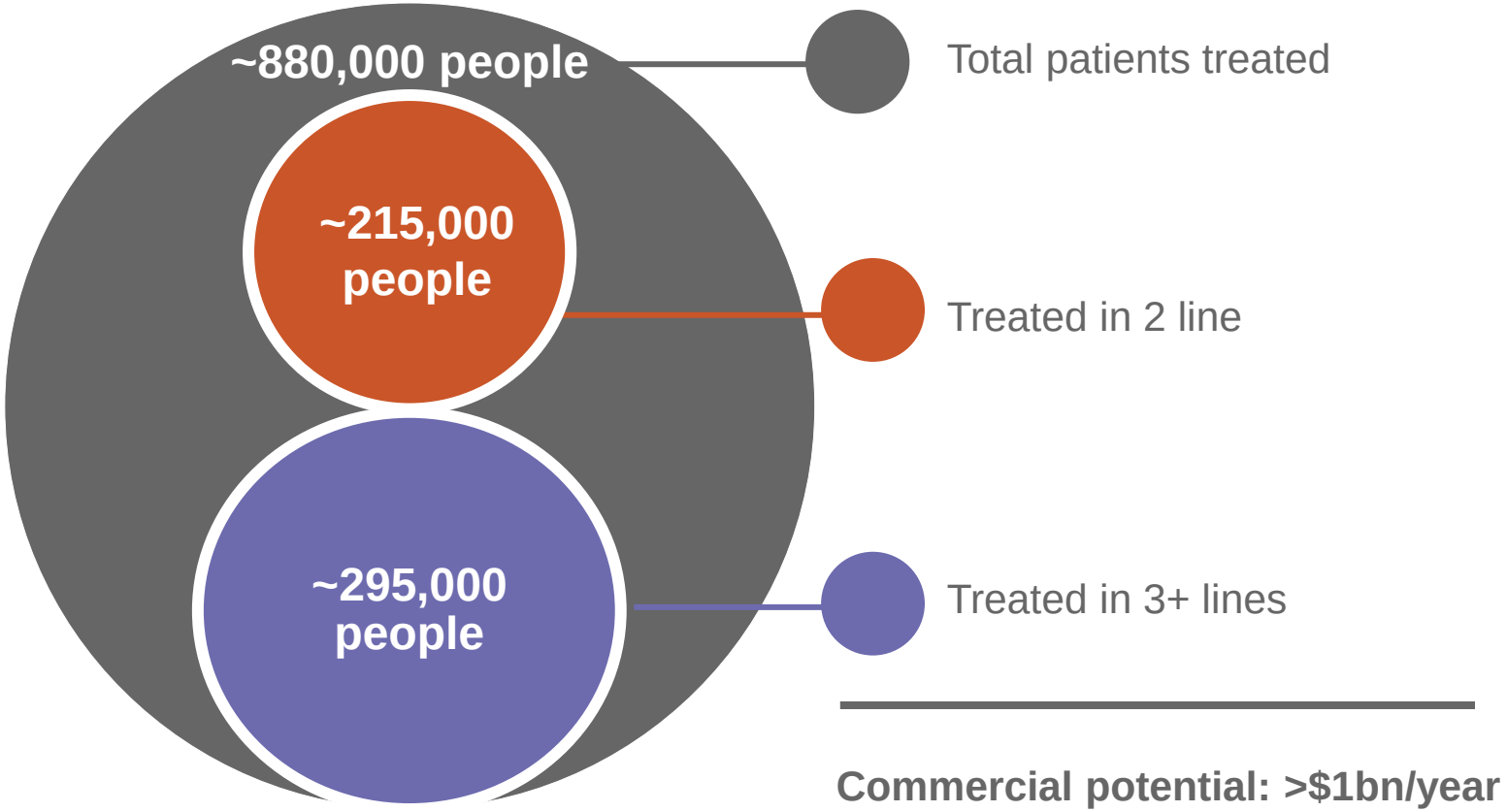
Principal Investigator: Dan Vogl, MD MSCE, Abramson Cancer Center Philadelphia, University of Pennsylvania

Status: Part A1 and B1 completed

- Patients (N = 16): median 8 previous lines of treatment, relapsed/refractory to PI:s, IMiD:s and CD38s
  - Safety and tolerability profile confirmed - no unexpected safety issues
  - Stable disease with single agent tasquinimod (N=3/10)
  - Responses to tasquinimod in combination with IRd (N=2/6) incl confirmed durable partial resonse (PR)
- ➢ Expansion cohort (B2) ongoing, expected results in H2, 2024

Abbrev: MTD - Maximum Tolerated Dose, ORR – Objective Response Rate, IRd – ixazomib, lenalidomide, dexamethasone
Clinicaltrial.gov: NCT04405167 **Reference**: Vogl D. et al American Society of Clinical Oncology 2023

Multiple Myeloma: Market Driven by Novel Treatments



Commercial potential: >$1bn/year

→ Duplet → Triplet → Quadruplet → Quintuplet multiple myeloma drug combination regimens

Eight major markets: $22bn in sales in 2027

Tasquinimod - novel, safe oral therapy to be used in combinations → opportunity in earlier lines of treatment

Source: GlobalData March 2019, 8 Major Markets (US, EU5, Japan, China). Presented data are based on 2027 forecast numbers

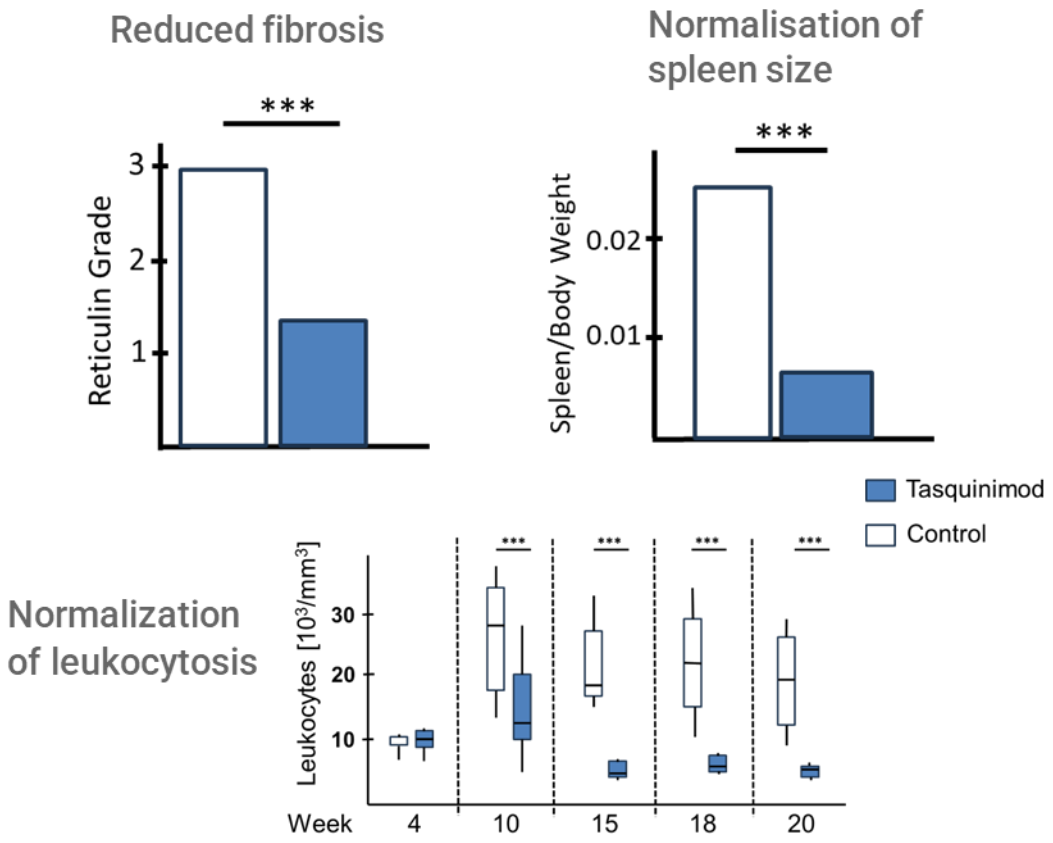
Myelofibrosis: Rare Blood Cancer

Myelofibrosis (MF) – In brief

- A rare blood cancer with an annual incidence of 0.4 - 1.3 cases per 100 000 people in Europe
- Market estimated to above USD 2.9 billion*
- Abnormal production of blood-forming cells replacing healthy bone marrow with scar tissue (fibrosis)
- Symptoms include anaemia, changes in white blood cell counts, enlargement of the spleen and increased risk for infections
- Associated with shortened survival due to bone marrow failure and transformation into acute leukaemia
- Current treatments: bone marrow transplantation, JAK inhibitors and therapies to manage anaemia

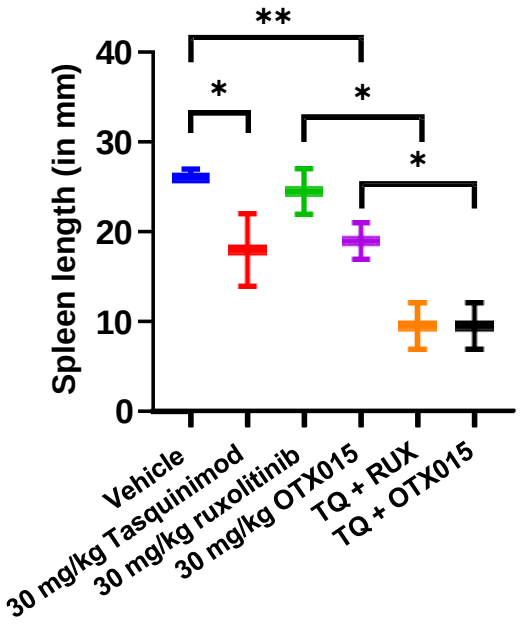
High medical need for disease modifying treatment

Tasquinimod Ameliorates Hallmarks of MF in a Mouse model

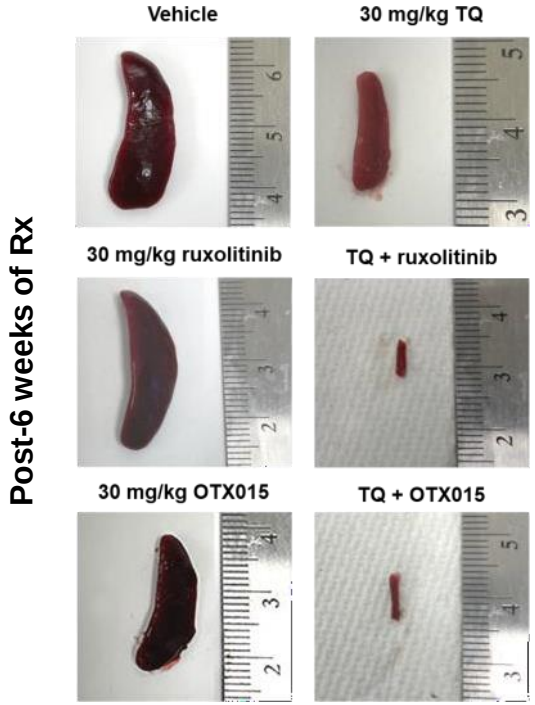


Combination with Tasquinimod and a BET inhibitor or a JAK inhibitor is Effective in a Mouse Model of MF*

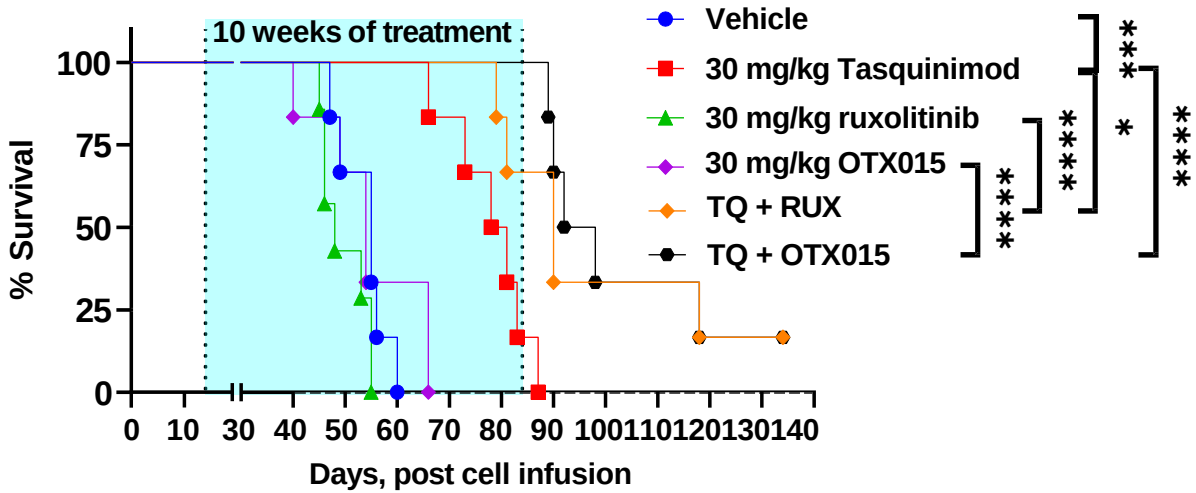
Reduced spleen length



Reduced spleen size



Increased survival



* PDX model of post-MPN sAML

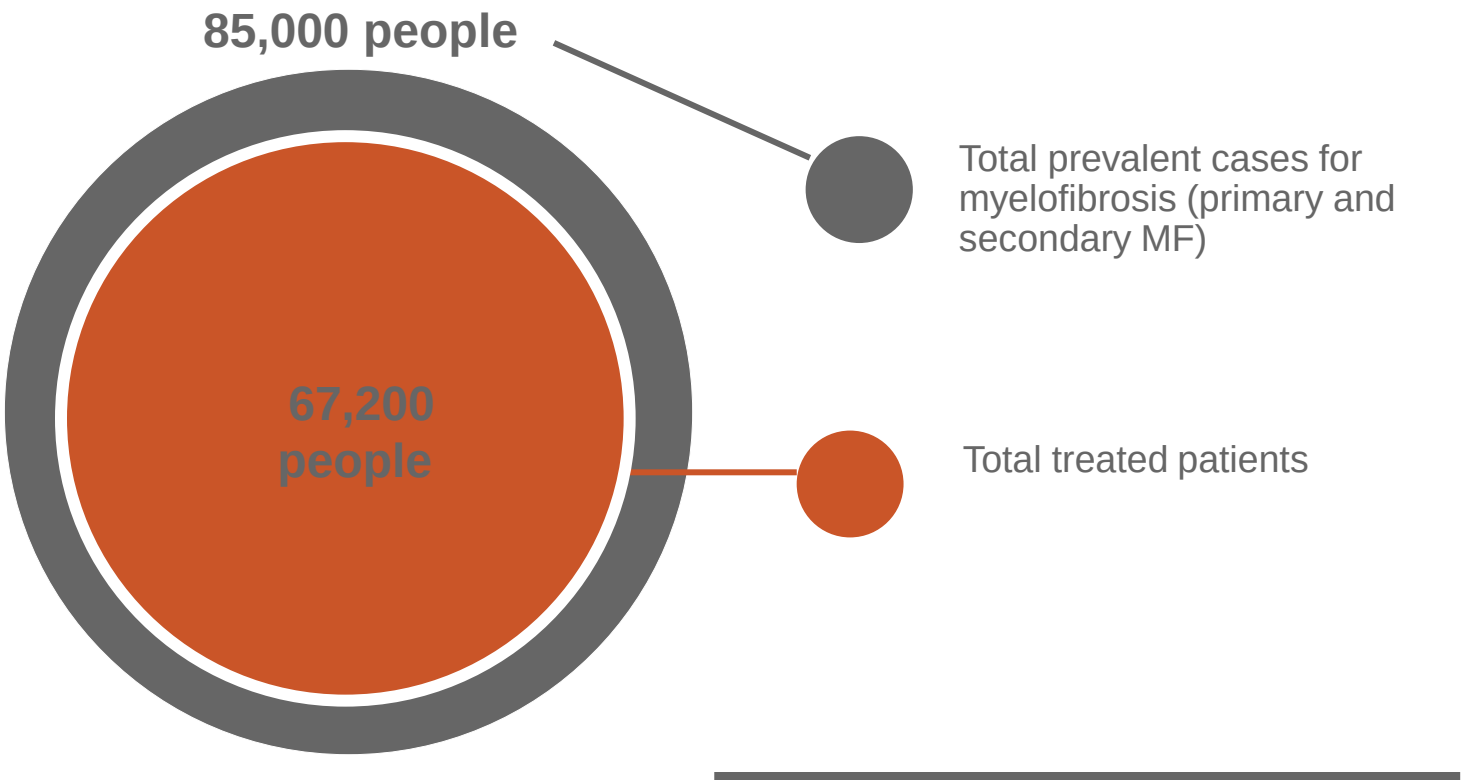
Abbrev: JAK inhibitor - Janus kinase inhibitors, TQ – tasquinimod, RUX – ruxolitinib, BET inhibitor - bromodomain and extra-terminal domain inihibitor (e.g. OTX015)
Source: Fiskus W.C., et al. Blood (2023) 142 (Supplement 1): 741

Tasquinimod: Development in Myelofibrosis

- Global patent license agreement between Active Biotech and Oncode Institute/Erasmus MC since Feb 2022
  - Clinical PoC with tasquinimod alone in Europe, to start in 2024
  - Study funded by Oncode Institute
  - To be conducted by HOVON in the Netherlands and Germany

- Collaboration with MD Anderson
  - Preclinical program ongoing – Oral presentation at ASH 2023 in December 2023
    - Tasquinimod alone or in combination with JAKi or BETi significantly improves survival
  - Clinical PoC with tasquinimod alone and in combination with JAKi, planned start 2024

Myelofibrosis: Need for Disease Modyfing Treatment



- **Major unmet medical need**
- **Only one drug class approved**

Commercial potential: USD 750 million /year

Eight major markets: USD 2.9 bn in sales in 2031

Source: GlobalData March 2023, 8 Major Markets (US, EU5, Japan and China). Presented data are based on 2031 forecast numbers

Laquinimod: Novel Treatment for Eye Disorders

Active Biotech

Core focus

Non-infectious uveitis

Laquinimod induces immune tolerance by targeting antigen presenting cells

- Clinical Ph I study testing the safety of an eye drop formulation completed

High value indications

Eye disorders with excessive neovascularization

Laquinimod reduces the pro-inflammatory and angiogenic response by targeting monocytes/macrophages and microglia

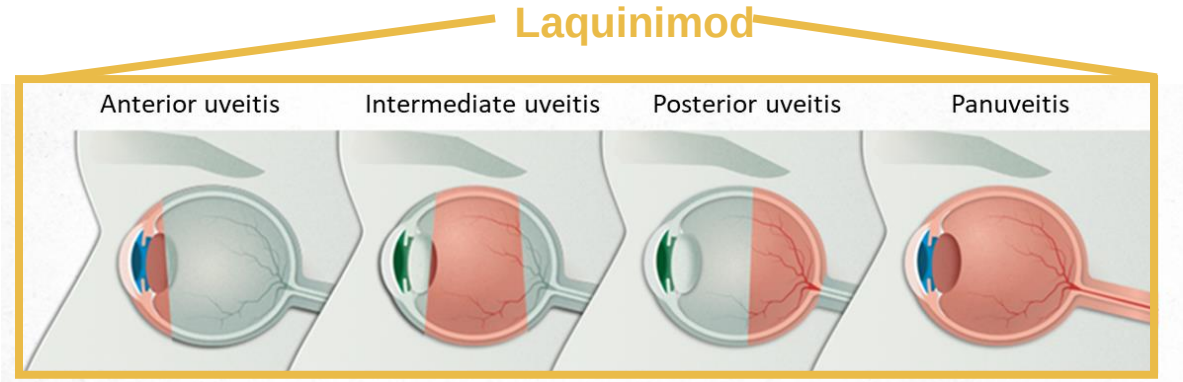
- Preclinical PoC established

- Clinical proof of concept shown through significant effects on relapse related endpoints in MS
- Regulatory package of preclinical safety and clinical safety (>14,000 person-years of exposure)
- Full commercial scale CMC documentation and pharmaceutical grade drug substance
- Exclusivity by patent and patent applications relating to medical use, manufacturing and formulation to at least 2042

Abbrev: PoC – Proof of Concept; MS – Multiple sclerosis; CMC - Chemistry, Manufacturing and Controls

Non-Infectious Uveitis: High Medical Need

- Standard treatments
  - Corticosteroids: local and systemic
  - Immunosuppressants
  - Monoclonal antibodies
- High medical need for new therapy to improve efficacy and limit side effects
  - As a steroid-sparing regimen
  - Patients who do not respond to current therapies
  - **No eye drop formulation on the market for non-anterior uveitis**



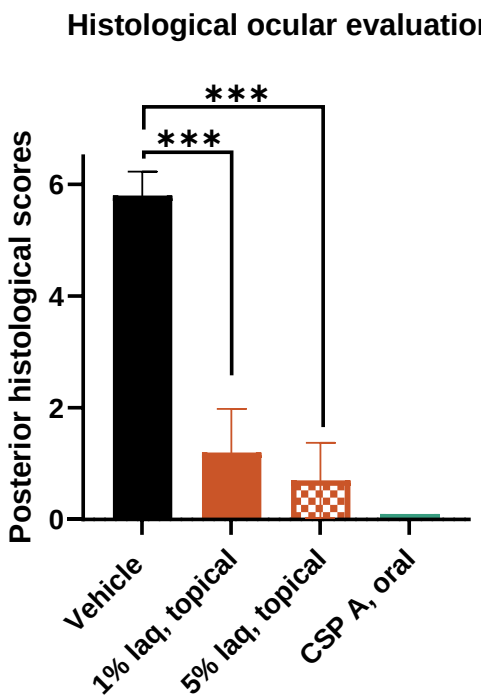
Current treatment of non-infectious uveitis

1st line of treatment
- Corticosteroids, topical, oral, intravitreal or periocular injection

2nd and 3rd line of treatment
- Immunosuppressants, oral
- Biologics – anti-TNFα antibodies (Humira®), subcutaneous

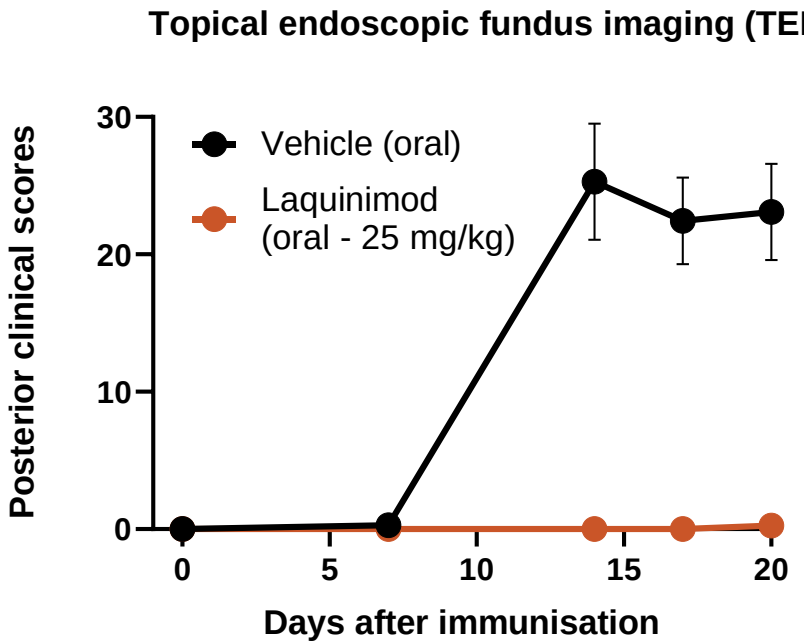
Laquinimod Works Both Topically and Orally

Topical laquinimod



Study design: EAU in Lewis rats, antigen - S-antigen, treatment days 7-16

Oral laquinimod



Study design: EAU in B10.RIII mice, antigen – IRBP 161–180, treatment days 0-20

Inhibition of experimental uveitis by laquinimod is associated with:

- Reduction of pro-inflammatory T cells and cytokines
- Increase of anti-inflammatory regulatory T cells

Abbrev. Laq – laquinimod, EAU- Experimental Autoimmune Uveitis, IRBP – Interphotoreceptor Retinoid Binding Protein
Source: Rachel Caspi et al. J Immunol May 1, 2020, 204 (1 Supplement) 150.18

Laquinimod Development Program in Eye Disorders

- Innovative gel like eye drop formulation*, developed, optimized and manufactured
- Available IND regulatory package complemented with required pre-clinical eye toxicity & tolerance studies
- Safety and tolerability confirmed in clinical Phase I study in healthy subjects completed

- Full commercial scale CMC documentation available
- Safety data from > 5,000 exposed persons
- Full IND regulatory documentation available
- Substantial pre-clinical proof-of-principle

Abbrev: CMC - Chemistry, Manufacturing and Controls; IND - Investigational new drug
*Patent application submitted

Safety and Tolerability Profile of Laquinimod Eye Drops Confirmed in Healthy Subjects

Subjects (N=54)

Single-Ascending Dose

- Laquinimod or placebo

Dose-escalation based on
- Adverse events
- Eye examinations
- Safety laboratory testing

Multiple Dose

- Laquinimod or placebo

Dose/Duration:
- Once daily for up to 21 days

Assessments:
- Adverse events, eye examinations, safety laboratory

- Doses studied expected to reach therapeutic concentrations in the eye
- Favourable safety and tolerability profile confirmed in healthy subjects

clinicaltrials.gov NCT05187403
Garhöfer et al International Ocular Inflammation Society (IOIS) 2023

Laquinimod: Clinical Development in Uveitis

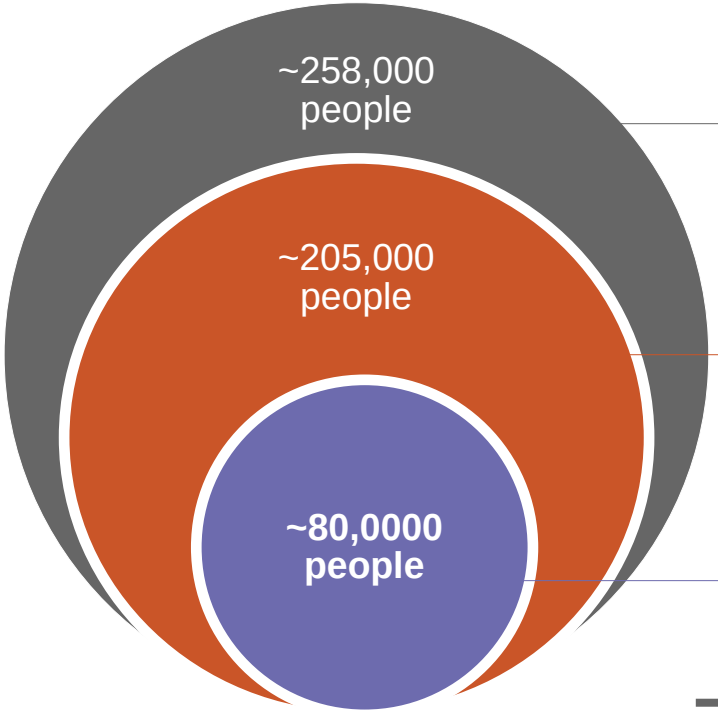
✓ Generate data on safety and tolerability of laquinimod eye drops in healthy subjects
  - Safety and tolerability confirmed in completed phase I study

- Confirm biodistribution in the eye after ocular administration to patients
  - Study to start in Q1 2024 at Byers Eye Institute in Stanford University, USA with Principal Investigator Quan Dong Nguyen, MD, Professor of Ophthalmology, Medicine, and Pediatrics, Stanford University School of Medicine

- Continue clinical development together with partner for a registrational clinical phase II/III study in patients with Non-anterior Non-infectious uveitis (NA-NIU)

Uveitis: Significant Opportunity

Significant opportunity in segment of non-infectious non-anterior uveitis in 9MM, forecasts for 2029



Total diagnosed prevalent cases

Total treated cases (1LoT: corticosteroids)

Corticosteroid failed patients, 2LoT+ treatments

Commercial potential: >$0.5 bn/year

- **Corticosteroids only effective in 60%**
- **Clinical consequences serious**

- **Major unmet medical need**
- **Shortage of licensed therapies**
- **High cost of anti-TNF therapy**

Abbrev: LoT – Line of treatment
Source: GlobalData June 2021, 9 Major Markets (US, EU5, Japan, Canada and Australia). Presented data are based on 2029 forecast numbers

Naptumomab: Tumor Directed Immunotherapy

Combination with checkpoint inhibition

Preclinical data suggest synergy with checkpoint inhibitors

- Ph-Ib/IIa combination with anti-PDL-1 durvalumab after Obi pretreatment in selected tumors

Combination with chemotherapy

Preclinical data suggest synergy with chemotherapy

- Ph-IIa combination with docetaxel after Obi pretreatment in Non-small cell lung cancer (NSCLC) ongoing

Combination with CART Cell Treatment

Preclinical data suggest synergy with CAR T cell treatment

- Preclinical activities ongoing

- ✓ Licensee agreement for global development and commercialization with NeoTX LTD, 2016
  - ✓ Deal value of $71 million contingent upon achievement of clinical and regulatory milestones
  - ✓ Progressive, double-digit royalties on future net sales based on a 15-year royalty period
- ✓ Signals of long-term clinical efficacy and established clinical safety (>300 patients)
- ✓ Substantial market opportunity within immuno-oncology reflected by combined global sales of checkpoint inhibitors of USD 31 billion in 2021. The strong sales development is expected to continue*
- ✓ Patent protection relating to medical use, manufacturing and formulation up to at least 2036

*Global Newswire February 2020
Abbrev: Obi - Obinutuzumab

Naptumomab: Clinical Studies

- Phase IIa study of naptumomab + docetaxel in lung cancer (NCT04880863)
  - Patients (N=35): Progressive NSCLC, no prior docetaxel, prior exposure to checkpoint inhibitor
  - Status: Second stage ongoing following successful completion of the first stage, which required at least 2 responses out of 10 patients
  - Results: Expected H1 2024
- Phase Ib/IIa study of naptumomab + durvalumab in selected tumors (NCT03983954)
  - Patients (N=59): Previously treated solid tumors with high likelihood of 5T4 expression
  - In collaboration with AstraZeneca
  - Status: Enrollment completed, and interim results published 2023
  - Cohort expansion in esophageal cancer planned to start H1 2024*
- Phase I study of naptumomab + pembrolizumab in urothelial cancer
  - Planned*

Treatment and Endpoints
Naptumomab + Docetaxel after Obinutuzumab pre-treatment

Endpoints:
- Primary: ORR at 24 months
- Secondary: Disease control rate, response duration, PFS at 6 and 12 months and OS

Treatment and Endpoints
Naptumomab + Durvalumab dose escalation and cohort expansion at MTD after Obinutuzumab pre-treatment

Endpoints:
- Primary: Safety and tolerability, MTD
- Secondary: Preliminary anti-tumor activity

* Timing of start uncertain due to current geopolitical situation

NSCLC – Non-Small Cell Lung Cancer, ORR – Objective Response Rate according to iRECIST, PFS – Progression Free Survival, OS – Overall Survival

Safety and Preliminary Activity of Naptumomab Estafenatox (NAP) and Durvalumab in Patients with Advanced or Metastatic Solid Tumors Interim Results from a Phase Ib Trial

Poster presentation at AACR 2023

- 59 patients with various advanced/metastatic solid tumors and a median of 3 prior lines
- Recommended phase II dose (RP2D) established at 10mcg/kg NAP
- NAP in combination with durvalumab is generally well tolerated, with limited toxicity, mainly Grade 1-2 injection related reactions
- Pretreatment with Obinutuzumab prevented the formation of Anti-Drug-Antibodies and preserved NAP plasma levels
- Responses were seen, lasting for 1 year or longer including complete responses (CR) in patients where response to single agent check point inhibitor was not expected
  - 4 durable responses in 42 evaluable patients (ORR 10%)
  - 4 patients had stable disease with median duration of 15 months (CBR 19%)
- Planned cohort expansion in patients with esophageal cancer

American Academy for Cancer Research, IRR – Infusion Related Reaction, ORR – Objective Response Rate, DoR – Duration of Response, CBR – Clinical Benefit Rate (includes ORR+Stable disease)

Projected Clinical Milestones Through 2024

Tasquinimod

- Ph Ib/IIa combination with IRd in multiple myeloma: Final results H2 2024
- Ph II Myelofibrosis
  - Start of study in Europe, Q3 2024
  - Start of study in US, H1 2024

Laquinimod

- Clinical biodistribution study of eye drop
  - Start of study, Q1 2024, results, H2 2024

Naptumomab

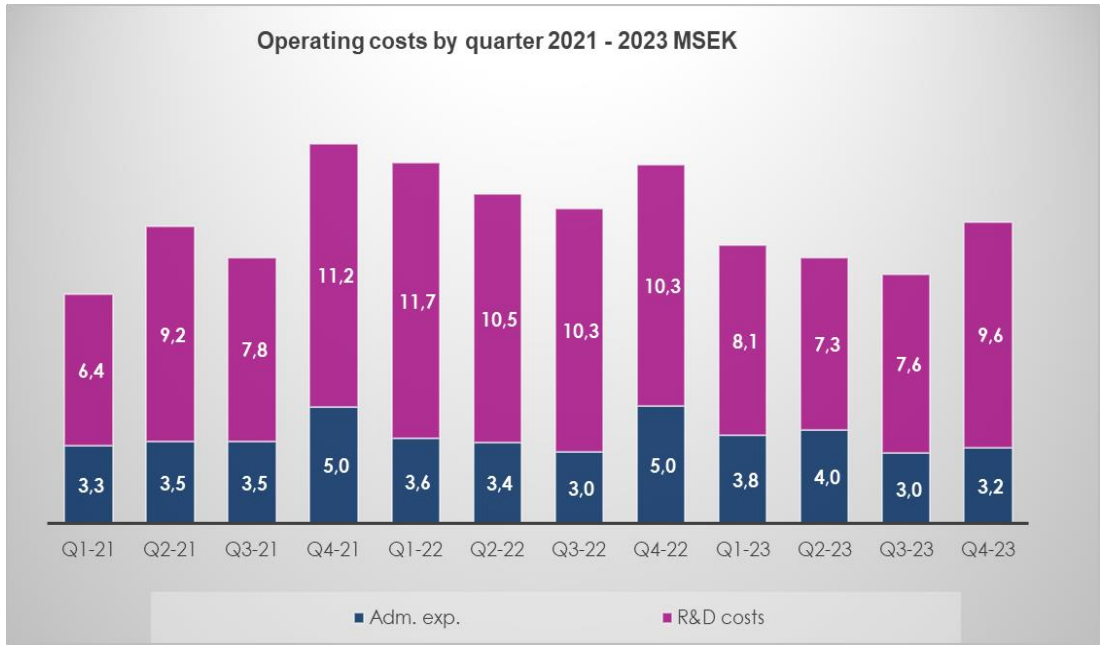
- Ph IIa combination with docetaxel in lung cancer: Results H1 2024
- Ph Ib/II combination with durvalumab
  - Start of cohort expansion in esophageal cancer 2024*
- Ph I combination with pembrolizumab in urothelial cancer: Planned*

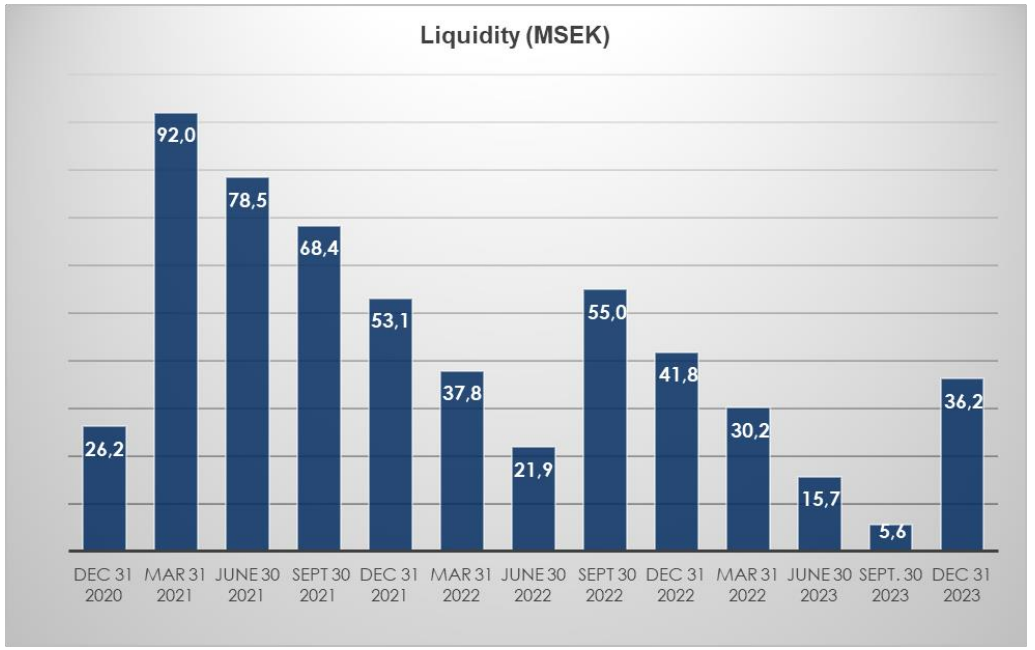
* Timing of start uncertain due to current geopolitical situation

Abbrev: IRd – ixazomib, lenalidomide, dexametasone; MM – multiple myeloma, IRd – Ixazomib, lenalidomide, dexamethasone, IOIS – International Inflammation Society

Financials For the Period January – December, 2023

- Operating expenses January – December, 2023 MSEK 46,5 (57,9) a 24% reduction reflecting reduced clinical and CMC costs.
- Rights issue concluded in Q4, 2023 added 41,8 MSEK to liquidity after issue costs
- Available cash at Dec. 31, 2023 - MSEK 36,2





Management

Helén Tuvesson

President & CEO

Born 1962. CEO since 2017.

Education: MSc, PhD in cell and molecular biology in medical science from Lund University.

Other current assignments: Chairman of Active Security Trading AB and Actinova AB. Board member of Mendus AB.

Shareholding in the company: 270,312 shares.

Hans Kolam

CFO

Born 1951. CFO since 2000.

Education: B.Sc in Business Administration from Uppsala University.

Other current assignments: Specially authorized signatory of Active Biotech AB (publ). Board member of Active Security Trading AB and Actinova AB.

Shareholding in the company: 193,648 shares (of which 6,930 shares via related parties).

Erik Vahtola

CMO

Born 1976. CMO since 2022.

Education: Medical Doctor (MD) and PhD in Pharmacology from University of Helsinki and MSc in Cell biology from Åbo Akademi.

Other current assignments: -

Shareholding in the company: 98,052 shares.

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