AB Science Webconference

28 February 2022

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Masitinib filing in the treatment of ALS in Canada under the NOC/c procedure

Notice of Compliance with Conditions (NOC/c) policy criteria

- Market authorization under the NOC/c (Notice of Compliance with Conditions) policy allows Health Canada to provide earlier market access to potentially life-saving drugs

- NOC/c status eligibility is restricted to:

  - ✓ New drug therapies intended for the treatment of serious, life-threatening or severely debilitating diseases
  - ✓ For which there is no alternative therapy available on the Canadian market
  - ✓ Where the new product represents a significant improvement in the benefit/risk profile over existing products

- A pre-assessment performed by an Adjudicating Committee is necessary before being granted authorization to file under NOC/c policy

- If granted, an NOC/c is authorization to market a drug with conditions. Such conditions will be discussed with Health Canada during the procedure

The Health Canada pre-assessment concluded that masitinib fulfills the criteria for filing and advance consideration under the NOC/c policy

- **This pre-assessment was made based on a pre-submission package sent by AB Science including, efficacy data of study AB10015, long-term survival data (75 months average follow-up from diagnosis) of study AB10015, and safety data**

- **Health Canada considered that** *[…] ALS is a serious, life-threatening and severely debilitating disease, with a median survival of 2 years after diagnosis*

- **Health Canada considered the promising evidence for masitinib 4.5 mg/kg/day when added to riluzole therapy in the treatment of ALS:**

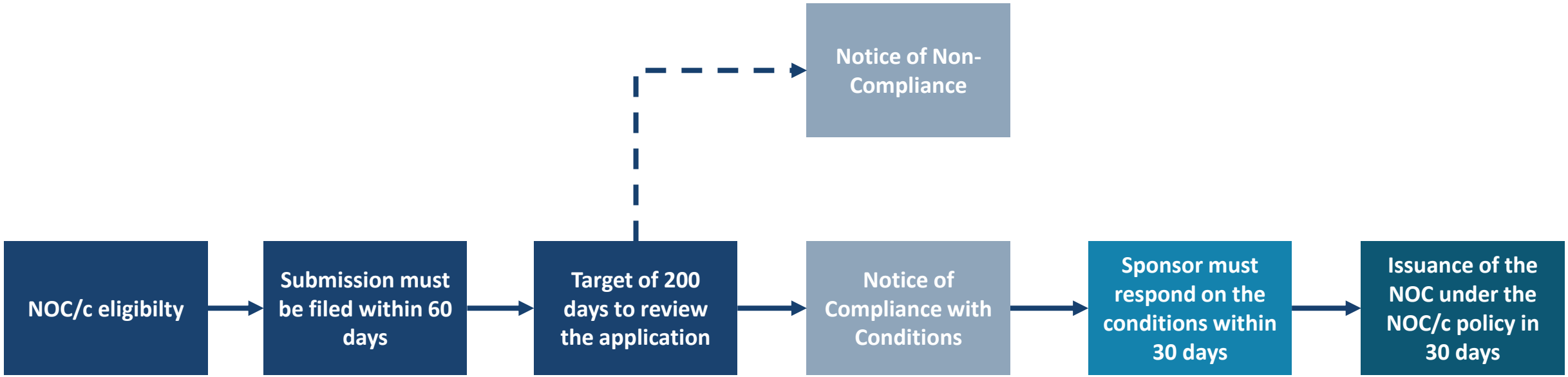
  - ✓ **Clinical benefit on the primary endpoint :** *[…] study AB10015 reported clinical benefit of the primary endpoint, change in ALSFRS-R from baseline to Week 48 (ΔALSFRS-R). In ALS patients with disease progression <1.1 points/month (normal progressors) prior to treatment initiation, masitinib at 4.5 mg/kg/day significantly decreased decline in ΔALSFRS-R 48 when added to background riluzole therapy, with a between-group difference of 3.4 (95% CI: 0.65-6.13), p=0.016 […]*

  - ✓ **Significant delay in disease progression :** *[…] the secondary endpoint of progression-free survival (PFS), defined as death or a disease progression corresponding to ≥ 9-point deterioration of ALSFRS-R from baseline, also demonstrated a significant delay in disease progression for masitinib 4.5 mg/kg/day of 25% in normal progressors, p=0.016, with a median PFS of 20 months for masitinib and 16 months for placebo.[…]*

  - ✓ **Significant advantage of 25 months in median overall survival :** *[…] In a post hoc analysis, overall survival was assessed at a June 2020 cut-off date, corresponding to the end of a long-term post hoc follow-up period, at an average follow-up time from diagnosis of 75 months. A significant advantage of 25 months in median overall survival, from 69 to 44 months, and corresponding to a 44% reduction in the risk of death (HR: 0.56; 95% CI 0.32–0.96), p=0.036, was observed for patients receiving masitinib 4.5 mg/kg/day (n=45) compared to placebo (n=62), in the cohort of normal progressor patients with moderate ALS […]*

- **Finally, Health Canada considered there is no need of a head-to-head comparison with edaravone therapy :** *[…] There was no head-to-head trial to assess the efficacy of masitinib compared to edaravone. However, a recently published article demonstrated that time to non-invasive ventilation and survival probability did not significant differ in patients receiving IV edaravone compared to matched ALS patients on standard therapy […]*

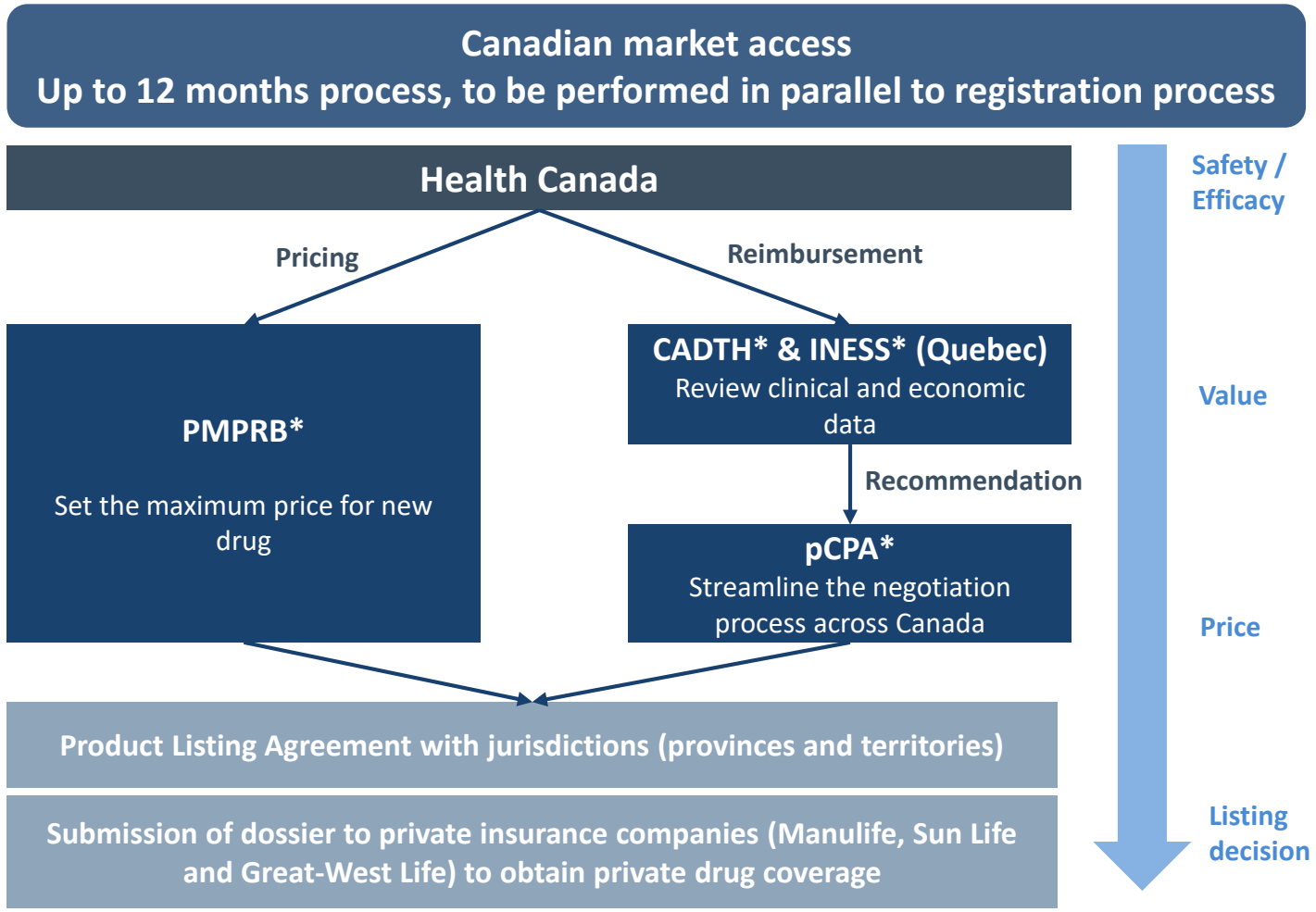
Final decision of Health Canada is expected by the end of 2022



AB Science will perform Market Access activities in parallel to registration process and will be able to supply ALS Canadian patients immediately

Supply of Canadian ALS patients

- **Canadian market size**:
  - ✓ 3,000 Canadians are currently living with ALS
  - ✓ Each year approximately 1,000 Canadians die from ALS
  - ✓ Each year approximately 1,000 Canadians are diagnosed with ALS
- **CMC capabilities**: AB Science has already the capabilities to supply 3,000 ALS patients per year



Edaravone is priced 130K€ (190CAN$) per year in Canada (before rebates)

** PMPRB: Patented Medicine Prices Review Board*
CADTH: Canadian Agency for Drugs and Technologies in Health
INESS: Institut national d'excellence en santé et en services sociaux
pCPA : Pan-Canadian Pharmaceutical Alliance

So far, AB Science prepares a stand-alone commercialization strategy in Canada

- The number of ALS centers is limited in Canada (below 20)
- ALS centers are mainly located in 11 cities
- An in-house salesforce should be sufficient to service ALS centers in Canada

Regulatory status with FDA and EMA

- Following Health Canada decision, AB Science intends to discuss/rediscuss
  - ✓ Conditional approval with EMA
  - ✓ Accelerated approval with FDA

- The discussion will be based on:
  - ✓ Efficacy data of study AB10015, with new ex-post analyses
  - ✓ Long-term survival data (75 months average follow-up from diagnosis) of study AB10015, which is new data
  - ✓ Safety data
  - ✓ Validated and published masitinib mechanism of action

Update on clinical program across indications

Update on Masitinib - Amyotrophic Lateral Sclerosis (ALS)

Confirmatory Phase 3 study

- **Study status**: Actively recruiting
- **Primary endpoint:** Change in the ALSFRS-R score
- **Enrolment:** 550 patients
- **Duration:** 48 weeks
- **Dosing**:
  - ✓ Masitinib 4.5mg titrated
  - ✓ Masitinib 6.0mg titrated
  - ✓ Placebo
- **Study publication**:
  - ✓ Phase 2B/3 study: Mora JS, Genge A, Chio A, et al. Amyotroph Lateral Scler Frontotemporal Degener. 2020;21(1-2):5-14.
  - ✓ Long-term survival: Mora JS, Bradley WG, Chaverri D, et al. Ther Adv Neurol Disord. 2021;14:17562864211030365.
- **Impact of registration in Canada on study timing**: Marginal impact on study completion timing

Market and competition

- **Competitive landscape**:
  - ✓ Registered drugs : riluzole, edaravone (IV)
  - ✓ Drugs in development : AMX0035 (Amylyx), edaravone (oral)
- **Targeted patients**:
  - ✓ Europe : 30,000
  - ✓ US : 20,000

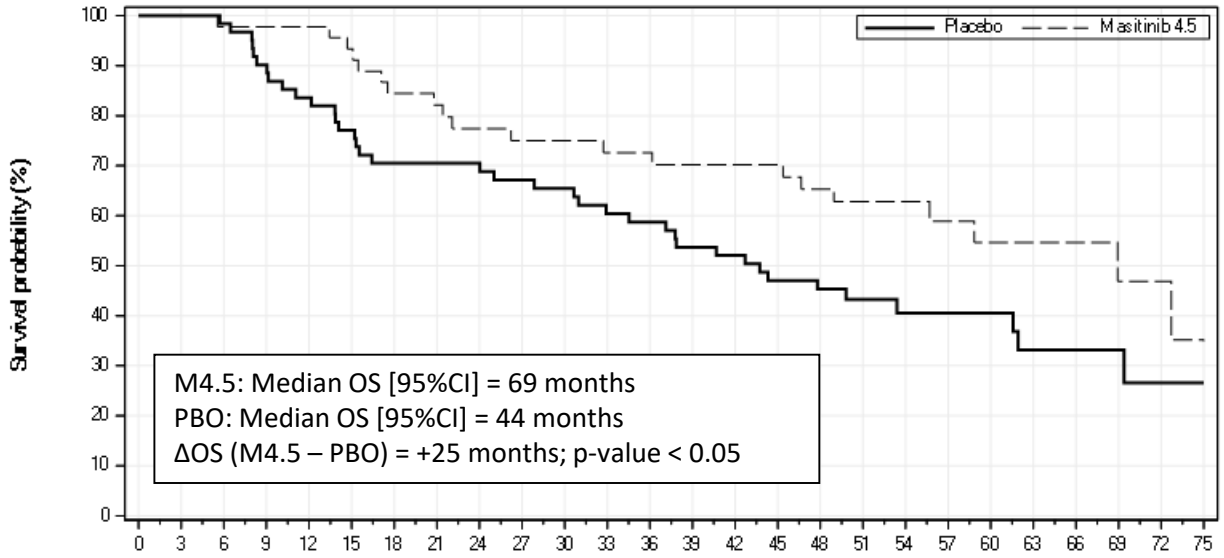
Compassionate use

- Compassionate use is not possible until last patient last visit (LPLV) of the current confirmatory study. Otherwise risk of no recruitment or patient discontinuation

In ALS, long-term survival follow-up showed a significant survival benefit of +25 months when treatment was initiated early

+ 25 months in median Overall Survival in patients with moderate ALS

Kaplan–Meier survival curves from masitinib study AB10015 long-term survival analysis progressors - Masitinib 4.5mg/kg/day



Moderate ALS (≥2 each baseline ALSFRS-R item; ; ΔFS<1.1)

Update on Masitinib - Progressive forms of Multiple Sclerosis

Confirmatory Phase 3 study

- **Study status**: Authorized in France and Sweden (announced publicly), recruitment to start imminently
- **Primary endpoint:** EDSS progression over 96 weeks
- **Enrolment:** 800 patients
- **Duration:** 96 weeks
- **Dosing**:
  - ✓ Masitinib 4.5mg titrated
  - ✓ Placebo
- **Study publication**: Phase 2b/3 study published : Vermersch P, Brieva-Ruiz L, Fox RJ, et al. Neurol Neuroimmunol Neuroinflamm 2022;9:e1148.

Market and competition

- **Competitive landscape**:
  - ✓ Registered drugs : Ocrevus (Roche/Genentech)
  - ✓ Drugs in development : BTK inhibitors
    - Tolebrutinib (Sanofi)
    - Fenebrutinib (Roche)
    - Orelabrutinib (Biogen)
    - Evobrutinib (Merck)
- **Targeted patients**:
  - ✓ Europe : 300,000
  - ✓ US : 200,000

There is a tremendous unmet need, with no approved drugs for non-active SPMS and only one for PPMS

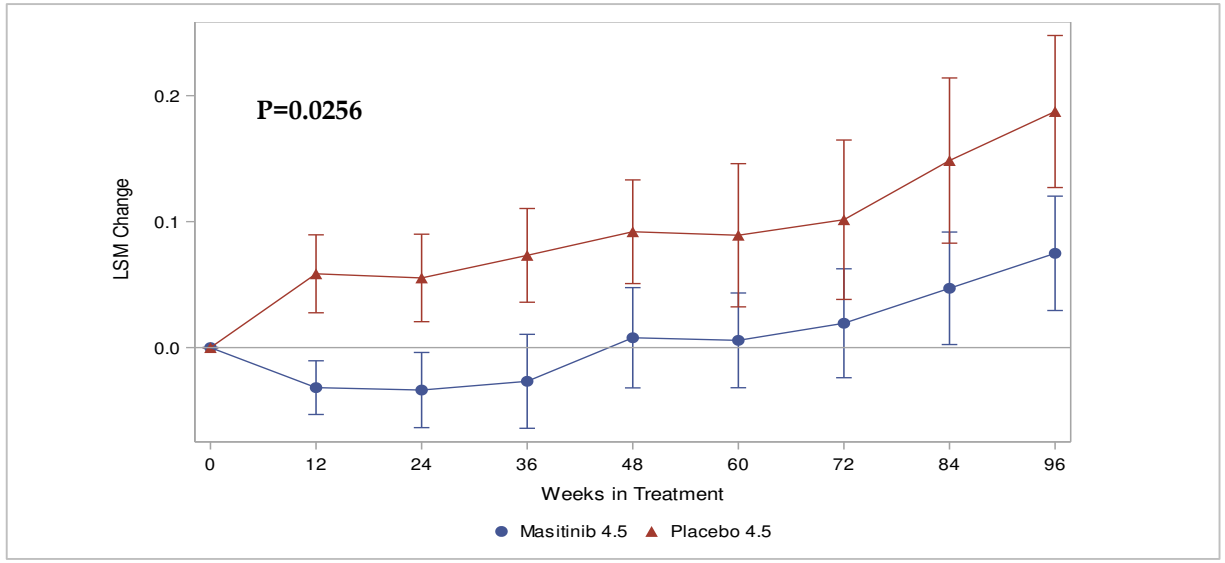
	Manufacturer	Masitinib Positioning		Label		First approved
		Primary Progressive MS	Non-active Secondary Progressive MS*	Active Secondary Progressive MS	Relapsing Remitting MS	
Distribution of patients *(Estimated Nbr of patients Europe + USA)*		**15%** *(~ 150 000)*	**35%** *(~ 350 000)*	**10%** *(~ 90 000)*	**40%** *(~ 400 000)*	
Total number of drugs registered †		**1**	**0**	**19**	**19**	
Ponvory (ponesimod)	Janssen Pharma			X	X	2021
Kesimpta (ofatumumab)	Novartis			X	X	2020
Bafiertam (monomethyl fumarate)	Banner Life Sciences			X	X	2020
Zeposia (ozanimod)	BMS			X	X	2020
Mayzent (siponimod)	Novartis			X	X	2019
Vumerity (diroximel fumarate)	Alkermes / Biogen			X	X	2019
Ocrevus (ocrelizumab)	Roche / Genentech	X		X	X	2017
Mavenclad (cladribine)	EMD Serono / Merck			X	X	2017
Plegridy (peginterferon beta-1a)	Biogen			X	X	2014
Tecfidera (dimethyl fumarate)	Biogen			X	X	2013
Aubagio (Teriflunomide)	Sanofi-Aventis			X	X	2012
Gilenya (fingolimod)	Novartis			X	X	2010
Extavia (interferon beta-1b)	Novartis			X	X	2008
Tysabri (natalizumab)	Biogen			X	X	2004
Lemtrada (alemtuzumab)	Sanofi / Genzyme			X	X	2001
Rebif (interferon beta-1b)	Serono			X	X	1998
Avonex (interferon beta-1a)	Biogen			X	X	1996
Copaxone (glatiramer acetate)	Teva Pharms			X	X	1996
Betaferon / Betaseron (interferon beta-1b)	Bayer Healthcare			X	X	1993

** Non-active SPMS is a stage of MS that follows relapsing-remitting multiple sclerosis and that is characterized with an EDSS score progression ≥ 1 point without any relapse in the last 2 years.*

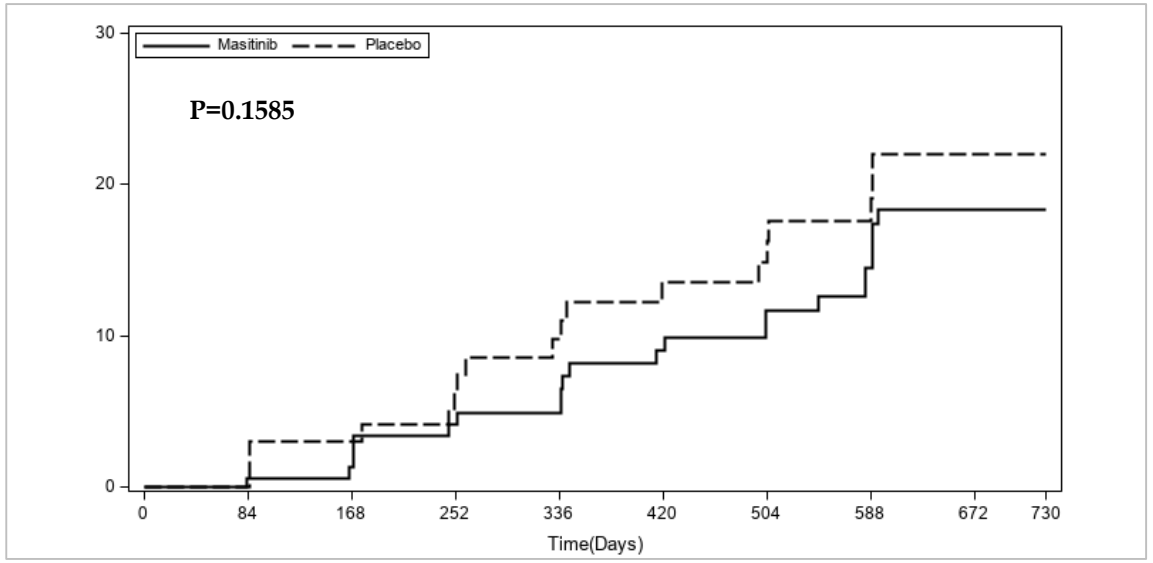
† BTK inhibitors tolebrutinib (Sanofi), fenebrutinib (Roche), orelabrutinib (Biogen), and evobrutinib (Merck) are not registered (phase 3 development in RMS and PMS)

Phase 2B/3 demonstrated significant benefit on disability progression with masitinib 4.5 mg/kg/day

Significant reduction in change in EDSS (Primary Endpoint)



37% risk reduction in confirmed EDSS progression (3 months)



- Time to confirmed EDSS progression was not the primary endpoint and was not powered to detect an significant effect
- Time to confirmed EDSS progression compares favorably with Ocrevus (registered drug) for which a 25% risk reduction in confirmed EDSS progression was observed

Update on Masitinib - Alzheimer's Disease

Confirmatory Phase 3 study

- **Study status**: In preparation, to be initiated in 2022
- **Primary endpoint:** ADAS-COG and ADCS-ADL change at week 24
- **Enrolment:** 600 patients
- **Duration:** 24 weeks
- **Dosing**:
  - ✓ Masitinib 4.5mg titrated
  - ✓ Placebo
- **Study publication**: Phase 2b/3 publication pending

Market and competition

- **Competitive landscape**: Aducanumab, but positioned on prodromal AD
- **Targeted patients**:
  - ✓ Europe : 3,000,000
  - ✓ US : 2,000,000

Masitinib is positioned in patients with mild and moderate dementia, which is different from other compounds

Disease severity	MMSE Score (mini mental state examination)
Prodromal	> 25
Mild	[21 – 25]
Moderate	[12 – 20]
Severe	< 12

Aducanumab

Prodromal AD
> 22 / > 24

Masitinib

Mild & Moderate AD
[12 – 25]

The Phase 2B/3 study demonstrated a statistically significant reduction in cognitive impairment based on ADAS-COG and a significant improvement on daily activity based on ADCS-ADL with masitinib 4.5 mg/kg/day

Significant effect on cognitive function after 24 weeks of treatment

Change in ADAS-Cog - ANCOVA Analysis (Full Analysis Set) - M4.5 vs Placebo

	Descriptive Statistics		Model Summary - LSM		Difference		
Treatment	n	Mean (SD)	LS Mean	95% CI	LS Mean (SE)	97.51% CI	p-value
Masitinib 4.5 mg/kg/day + SoC	182	-1.51 (5.81)	-1.46	(-2.46, -0.45)	-2.15 (0.59)	(-3.48, -0.81)	0.0003
Placebo + SoC	176	0.63 (5.35)	0.69	(-0.36, 1.75)			

Significant effect on daily activity after 24 weeks of treatment

Change in ADCS-Adl - ANCOVA Analysis (Full Analysis Set) - M4.5 vs Placebo

	Descriptive Statistics		Model Summary - LSM		Difference		
Treatment	n	Mean (SD)	LS Mean	95% CI	LS Mean (SE)	97.51% CI	p-value
Masitinib 4.5 mg/kg/day + SoC	182	0.51 (7.78)	1.01	(-0.48, 2.50)	1.82 (0.87)	(-0.15, 3.79)	0.0381
Placebo + SoC	176	-1.09 (9.17)	-0.81	(-2.36, 0.74)			

- **Imputation Model was used for missing Data (missing values are imputed by using the patient's previous non-missing score and data from other similar patients that have continued treatment)**
- **Sensitivity analysis based on Jump to reference imputation method is also statistically significant**

Update on Masitinib – Indolent Systemic Mastocytosis

Confirmatory Phase 3 study

- **Study status**: Actively recruiting
- **Primary endpoint:** Cumulative 75% response rate on baseline severe symptoms/handicaps among (pruritus, flush, depression) at week 24. Response on a handicap is defined as an improvement ≥ 75% for pruritus, flushes and depression.
- **Enrolment:** 140 patients
- **Duration:** 24 weeks
- **Dosing**:
  - ✓ Masitinib 6.0mg titrated
  - ✓ Placebo
- **Study publication**: Phase 3 study published : Lortholary O, Chandesris MO, Bulai Livideanu C, et al. Lancet. 2017 Feb 11;389(10069):612-620

Market and competition

- **Competitive landscape**:
  - ✓ Aggressive systemic mastocytosis (not the positioning of masitinib)
    - Registered drugs : Avapritinib (Blueprint), Midostaurin (Novartis)
  - ✓ Indolent systemic mastocytosis (positioning of masitinib)
    - Registered drugs : None
    - Drug in development : Avapritinib (Blueprint), BLU-263 (Blueprint)
- **Targeted patients**:
  - ✓ Europe : 40,000
  - ✓ US : 25,000

Update on Masitinib – MCAS

Previous proof of efficacy in mastocytosis wild-type

- Mast cell activation syndrome (MCAS) is a disease similar to mastocytosis but without the KIT D816V mutation
- Two mastocytosis Phase 2 studies were previously conducted :
  - ✓ A first study in patients who did not carry the D816V mutation
  - ✓ A second study in patients who did carry this mutation
- Result showed a significant change from Baseline in flushes score, depression score, and pruritus at Week 12, regardless of the presence of the mutation :

	Percentage change from baseline at Week 12		
	Flushes	Depression	Pruritus
Study with patients carrying the D816V mutation	55%	49%	4%
Study with patients not carrying the D816V mutation	64%	43%	36%

Phase 2 study in MCAS

- **Study status**: Authorized in France and US (announced publicly)
- **Primary endpoint:** Confirmed response at 50% on 3 handicaps (pruritus, flush, depression) at week 24
- **Enrolment:** 72 patients
- **Duration:** 24 weeks
- **Dosing**:
  - ✓ Masitinib 4.5mg titrated
  - ✓ Masitinib 6.0mg titrated
  - ✓ Placebo

Market and competition

- **Competitive landscape**:
  - ✓ Drugs in development : None
  - ✓ Registered drugs : None
- **Targeted patients**:
  - ✓ Europe : 300,000
  - ✓ US : 200,000

Masitinib - Three other confirmatory studies are expected to be launched sequentially following the initiation of the Alzheimer's Disease study

Next confirmatory studies to be launched	Expected timeline for initiation
Severe asthma uncontrolled by OCS or ICS	Second half of 2022
Locally advanced pancreatic cancer with pain	First half of 2023
Metastatic Castrate Refractory Prostate Cancer eligible to Docetaxel	First half of 2023

Update on Masitinib - Covid-19

AB20001
Hospitalized patients with moderate and severe COVID-19

- **Study status**: Actively recruiting
- **Primary endpoint:** Change in clinical status at day 15
- **Enrolment:** 200 patients (all patients are under standard of care, Dexamethasone)
- **Patient population**: Hospitalized patients with moderate and severe COVID-19
- **Dosing**:
  - ✓ Masitinib 4.5mg titrated
  - ✓ Placebo
- **End of study**: Results expected in 2022

AB21002
Ambulatory or hospitalized patients with symptomatic mild and moderate COVID-19

- **Study status**: Actively recruiting
- **Primary endpoint:** Viral load from baseline to day 10
- **Enrolment:** 77 patients
- **Patient population**: Ambulatory or hospitalized patients with symptomatic mild and moderate COVID-19
- **Dosing**:
  - ✓ Masitinib 3.0mg
  - ✓ Masitinib 4.5mg titrated
  - ✓ Masitinib 6.0mg titrated
  - ✓ Placebo
- **End of study**: Results expected in 2022

In case study AB20001 or study AB21002 is successful

- AB Science would seek for licensing with a big pharma and/or an agreement with nations to execute and finance a Phase 3 study (3,000 patients)
- CMC scale-up would take 12 months to serve million of patients and would need financing

Update on AB8939 – Acute Myeloid Leukemia

AB8939 differentiating factors

- New synthetic microtubule-destabilizing drug
- Able to overcome P-glycoprotein (Pgp) and myeloperoxidase (MPO) mediated drug resistance
- Developed for acute myeloid leukemia (AML), with potential to be developed in numerous oncology indications

Positive preclinical data

- Data from a highly resistant Ara-C patient derived xenograft (PDX) mouse model showed that AB8939, administered alone or in combination with Ara-C, increased survival relative to Ara-C alone
- Accompanying significant reduction of blasts in blood and decrease in tumor growth

Clinical study

- **Study status**: Authorized in France, Canada and USA (announced publicly)
- **Expected timelines**:
  - ✓ Phase 1 study (3 days): 2022
  - ✓ Phase 1 study (14 days, 28 days, 14 days in combination with azacitidine): 2023
  - ✓ Phase 2 pivotal study: 2024. This pivotal phase 2 study could lead to accelerated approval if hematological response is above 30%
- **Primary endpoint:**
  - ✓ Phase 1: MTD determination
  - ✓ Phase 2: Percentage of patients with hematological response

Update on financing and licensing strategy

With current financing commitments, AB Science has enough financial resources to launch commercialization of masitinib in ALS in Canada

- **25M€ commitment by historical shareholders, at the initiative of AB Science**:
  - ✓ Financing of 7.5M€ by a historical investor on February 27, 2022, through the issuance of convertible bonds with a conversion price of 14€ with less than 10% warrants at an exercisable price of 12.65€
  - ✓ 17.5M€ outstanding financing option by June 2022, at the initiative of AB Science

- **Research Tax credit:**
  - ✓ 2020 Research Tax credit to by received by end of Q1 2022: 3.3M€
  - ✓ 2021 Research Tax credit to by received by end of 2022: 3.2M€

- **EIB Covid-19 loan**
  - ✓ Amount: 15M€
  - ✓ Status: Signed, each tranch to be released at the initiative of AB Science
  - ✓ 3 tranches:
    - Tranche 1 (6M€) : Operational conditions already met
    - Tranche 2 (6M€) : Operational conditions already met
    - Tranche 3 (3M€) : Conditions of successful study and being referenced among potential Covid-19 treatment
  - ✓ The loan bears interest and warrants and is similar to a mezzanine financing

- **EIB second loan (all indications outside Covid-19)**
  - ✓ Amount: 30M€
  - ✓ Status: EIB confirmed interest, provided first tranche of Covid-19 loan is used. Negotiations to be finalized
  - ✓ 3 tranches:
    - Tranche 1 (10M€) : Operational conditions already met
    - Tranche 2 (10M€) : Operational conditions will be met in the next 12 months
    - Tranche 3 (10M€) : Operational conditions will be met in the next 12 months
  - ✓ The loan bears interest and warrants and is similar to a mezzanine financing

Update on licensing strategy

- The research of a licence is an objective of 2022 and is public
- The execution of this search is confidential
- An external financial service provider has been recruited to assist AB Science in this search
- Any licence, will be assessed over the current stand-alone scenario, globally or indication by indication or region by region

Q&A