Efficacy and Safety of Bimagrumab/BYM338 at 52 Weeks on Physical Function, Muscle Strength, Mobility in sIBM Patients (RESILIENT)

Purpose

To evaluate the efficacy, safety and tolerability of multiple doses of bimagrumab/BYM338 vs placebo, when administered intravenously (i.v.), on physical function, muscle strength, and mobility in patients with sporadic inclusion body myositis (sIBM).

Condition

- Sporadic Inclusion Body Myositis

Intervention

- Drug: BYM338/bimagrumab
- Drug: Placebo

Phase

- Phase 2
- Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: Randomized, Double-blind, Placebo-controlled, Dose-finding Study to Evaluate Efficacy, Safety, Tolerability of i.v. BYM338 at 52 Weeks on Physical Function, Muscle Strength, and Mobility in Sporadic Inclusion Body Myositis Patients

Resource links provided by NLM:

- Genetics Home Reference related topics: idiopathic inflammatory myopathy
- MedlinePlus related topics: Myositis
- U.S. FDA Resources

Further study details as provided by Novartis:

Primary Outcome Measures:

- Change from Baseline in 6 Minute Walking Distance Test (6MWD) meters to Week 52 [ Time Frame: Baseline, Week 52 ] [ Designated as safety issue: No ]
  
  Change from baseline to Week 52 in the distance a patient can walk in a set timeframe. 6 Minute Walking Distance Test measures the distance (in meters) that a patient can walk in a 6 minute timeframe.

Secondary Outcome Measures:

- Change from Baseline in lean body mass (LBM) at Week 52 [ Time Frame: Baseline, Week 52 ] [ Designated as safety issue: No ]
  
  Change from baseline to Week 52 in the total and appendicular lean body mass

- Change from Baseline in quadriceps Quantitative Muscle Testing (QMT) at Week 52 [ Time Frame: Baseline, Week 52 ] [ Designated as safety issue: No ]
  
  Change from baseline to Week 52 in quadriceps QMT.
- Change from Baseline in Patient-Reported Physical Function at Week 52 [Time Frame: Baseline, Week 52]
  [Designated as safety issue: No]
  Change from baseline to Week 52 in a patient reported outcome instrument.

- Rate of Fall Events [Time Frame: Baseline, Day 1, Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 84, 88, 92, 96, 100, 104, 108] [Designated as safety issue: Yes]
  Number of falls

- Change from Baseline in Short Physical Performance Battery score at Week 52 [Time Frame: Baseline, Week 52]
  [Designated as safety issue: No]
  Change from baseline to Week 52 in physical performance as measured by the Short Physical Performance Battery (SPPB).

- Safety and Tolerability of different i.v. BYM338 doses [Time Frame: Baseline, Day 1, Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, 76, 80, 84, 88, 92, 96, 100, 104, 108] [Designated as safety issue: Yes]
  Safety and tolerability

- Change from Baseline in 6MWD meters to Week 52 [Time Frame: Baseline, Week 52] [Designated as safety issue: No]
  Dose-response relationship

Estimated Enrollment: 240
Study Start Date: September 2013
Estimated Study Completion Date: November 2015
Estimated Primary Completion Date: November 2015 (Final data collection date for primary outcome measure)

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| Experimental: BYM338/bimagrumab High Dose
  60 patients who meet all inclusion criteria and none of the exclusion criteria will be treated with the BYM338 High Dose administered via intravenous infusion from Day 1 to Week 52, and up to Week 104. | Drug: BYM338/bimagrumab
  BYM338 will be administered via intravenous infusion to randomized patients beginning on Day 1 through Week 52, and up to Week 104. |
| Experimental: BYM338/bimagrumab Mid Dose
  60 patients who meet all inclusion criteria and none of the exclusion criteria will be treated with the BYM338 Mid Dose administered via intravenous infusion from Day 1 to Week 52, and up to Week 104. | Drug: BYM338/bimagrumab
  BYM338 will be administered via intravenous infusion to randomized patients beginning on Day 1 through Week 52, and up to Week 104. |
| Experimental: BYM338/bimagrumab Low Dose
  60 patients who meet all inclusion criteria and none of the exclusion criteria will be treated with the BYM338 Low Dose administered via intravenous infusion from Day 1 to Week 52, and up to Week 104. | Drug: BYM338/bimagrumab
  BYM338 will be administered via intravenous infusion to randomized patients beginning on Day 1 through Week 52, and up to Week 104. |
| Placebo Comparator: Placebo
  60 patients who meet all inclusion criteria and none of the exclusion criteria will receive matching placebo administered via intravenous infusion from Day 1 to Week 52, and up to Week 104. | Drug: Placebo
  Matching placebo will be administered via intravenous infusion to 60 randomized patients beginning on Day 1 through Week 52, and up to Week 104. |

**Eligibility**

- Ages Eligible for Study: 36 Years to 85 Years
- Genders Eligible for Study: Both
- Accepts Healthy Volunteers: No

**Criteria**

- **Inclusion Criteria:**
  - Diagnosed with sporadic inclusion body myositis;
  - Must be able to walk (assistive aids allowed, including intermittent use of wheelchair)

- **Exclusion Criteria:**
  - No other conditions that significantly limit ability to move around;
  - Must not be using corticosteroids. Must not have used systemic corticosteroid (at daily dose >=10mg prednisone) for the past 3 months;
  - Must meet cardiovascular requirements;
  - Must not be pregnant or nursing;
  - Must not have a chronic active infection (e.g., HIV, hepatitis B or C, tuberculosis, etc);
Other protocol-defined inclusion/exclusion criteria may apply

**Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT01925209

**Contacts**

Contact: Novartis Pharmaceuticals  +41613241111  Contact: Novartis Pharmaceuticals

**Sponsors and Collaborators**
Novartis Pharmaceuticals

**Investigators**
Study Director:  Novartis Pharmaceuticals  Novartis Pharmaceuticals

**More Information**
No publications provided

| Responsible Party: | Novartis (Novartis Pharmaceuticals) |
| ClinicalTrials.gov Identifier: | NCT01925209  History of Changes |
| Other Study ID Numbers: | CBYM338B2203 |
| Study First Received: | August 15, 2013 |
| Last Updated: | August 16, 2013 |

Health Authority:
- Australia: Department of Health and Ageing Therapeutic Goods Administration
- Belgium: Federal Agency for Medicinal Products and Health Products
- Denmark: Danish Medicines Agency
- France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)
- Germany: Paul-Ehrlich-Institut
- Italy: Ethics Committee
- Italy: National Monitoring Centre for Clinical Trials - Ministry of Health
- Japan: Pharmaceuticals and Medical Devices Agency
- Netherlands: Medicines Evaluation Board (MEB)
- Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
- Switzerland: Swissmedic
- United Kingdom: Medicines and Healthcare Products Regulatory Agency
- United States: Food and Drug Administration

Keywords provided by Novartis:
sporadic inclusion body myositis,  body mass,  myositis,  muscle function,  muscle wasting,  strength,  controlled clinical trial,  performance,  randomized,  physical function

Additional relevant MeSH terms:
- Myositis  Musculoskeletal Diseases
- Myositis, Inclusion Body  Neuromuscular Diseases
- Muscular Diseases  Nervous System Diseases

ClinicalTrials.gov processed this record on August 20, 2013