

## Title

The BELTRIMS registry: a unique Belgian registry on real-world safety and efficacy data of MS patients treated with new DMTs in Belgium

## Authors

**B. Willekens**<sup>1,2</sup>, V. Van Pesch<sup>3</sup>, M. D'Hooghe<sup>4</sup>, D. Dive<sup>5</sup>, B. Dubois<sup>6</sup>, R. Bouton<sup>7</sup>, M. Cambron<sup>8,16</sup>, B. Capron<sup>9</sup>, R. Crols<sup>10</sup>, B. Dachy<sup>11</sup>, F. Debruyne<sup>12</sup>, J. Debruyne<sup>13</sup>, D. Decoo<sup>14</sup>, V. Delvaux<sup>15</sup>, O. Deryck<sup>16</sup>, M. Dewil<sup>17</sup>, I. Dhollander<sup>18</sup>, A. De Pauw<sup>19</sup>, J.-A. Elozegi<sup>7</sup>, S. El Sankari<sup>3</sup>, A. Etxeberria Izal<sup>20</sup>, S. Goffette<sup>21</sup>, N. Govers<sup>22</sup>, D. Guillaume<sup>23</sup>, A.-G. Herbaut<sup>24</sup>, N. Jacquemotte<sup>25</sup>, P. Jacquerye<sup>26</sup>, G. Laureys<sup>13</sup>, N. Libbrecht<sup>27</sup>, E. Lommers<sup>28</sup>, F. London<sup>29</sup>, A. Maertens de Noordhout<sup>30</sup>, G. Nagels<sup>4</sup>, K. Peeters<sup>18</sup>, G. Perrotta<sup>30</sup>, R. Reznik<sup>23</sup>, S. Shalchian<sup>15</sup>, C. Swinnen<sup>31</sup>, E. Urbain<sup>32</sup>, K. Van de Velde<sup>33</sup>, D. Verhalle<sup>34</sup>, P. Seelldrayers<sup>9</sup>, and on behalf of the Belgian Study Group for Multiple Sclerosis, BSGMS, Belgium

<sup>1</sup>Antwerp University Hospital, Department of Neurology, Antwerp <sup>2</sup>University of Antwerp, Laboratory of Experimental Hematology, Vaccine & Infectious Disease Institute (VAXINFECTIO), Faculty of Medicine and Health Sciences, Antwerp, <sup>3</sup>Cliniques Universitaires Saint-Luc, Department of Neurology, Brussels, <sup>4</sup>National Multiple Sclerosis Center, Melsbroek, <sup>5</sup>CHU Liège - Sart Tilman B35, Unité de Neuro-Immunologie Clinique, Liège, <sup>6</sup>UZ Leuven and KU Leuven, Laboratory for Neuroimmunology, Department of Neurosciences, Leuven, <sup>7</sup>CHU Ambroise Paré, Department of Neurology, Mons, UZ Brussel, <sup>8</sup>Department of Neurology, Brussels, <sup>9</sup>CHU Charleroi, Department of Neurology, Charleroi, <sup>10</sup>ZNA Middelheim, Department of Neurology, Antwerp, <sup>11</sup>Hôpital Brugmann, Department of Neurology, Brussels, <sup>12</sup>GZA Ziekenhuizen, Department of Neurology, Antwerp, <sup>13</sup>UZ Gent, Department of Neurology, Gent, <sup>14</sup>AZ Alma, Department of Neurology, Sijsele, <sup>15</sup>Hôpital de la Citadelle, Department of Neurology, Liège, <sup>16</sup>AZ Sint-Jan Brugge Oostende, Department of Neurology, Bruges, <sup>17</sup>Imeldaziekenhuis, Department of Neurology, Bonheiden, <sup>18</sup>Jessa Ziekenhuis, Department of Neurology, Hasselt, <sup>19</sup>AZ Sint-Blasius, Department of Neurology, Dendermonde, <sup>20</sup>Clinique Saint-Michel, Department of Neurology, Brussels, <sup>21</sup>Clinique Saint-Joseph, Department of Neurology, Arlon, <sup>22</sup>AZ SintMaarten, Department of Neurology, Mechelen, <sup>23</sup>CNRF, Fraiture-en-Condroz, <sup>24</sup>Hôpital Erasme, Brussels, <sup>25</sup>Centre de Santé des Fagnes, Department of Neurology, Chimay, <sup>26</sup>Clinique SaintPierre, Ottignies, <sup>27</sup>AZ Sint-Lucas, Department of Neurology, Assebroek, <sup>28</sup>CHU de Liège - Sart Tilman B35, Liège, <sup>29</sup>CHU UCL Namur site Godinne, Department of Neurology, Yvoir, <sup>30</sup>Hôpital Erasme, Department of Neurology, Brussels, <sup>31</sup>Heilig-Hart Ziekenhuis, Department of Neurology, Mol, <sup>32</sup>Grand Hôpital de Charleroi, Department of Neurology, Charleroi, <sup>33</sup>AZ Sint-Nikolaas, Department of Neurology, Sint Niklaas, <sup>34</sup>AZ Sint-Jan Brugge-Oostende, Department of Neurology, Oostende, Belgium

**Introduction:** A unique Belgian registry of multiple sclerosis (MS) patients starting a new disease modifying treatment (DMT) was conceived and established in 2012 by the Belgian Study Group for Multiple Sclerosis (BSGMS). The registry is named BELTRIMS, short for 'Belgian Treatment in MS'.

**Aims:** We collect data independent from pharmaceutical companies in a single registry of Belgian MS patients, as opposed to having different registries for each new DMT. In doing so, we anticipate to detect unknown or rare side-effects, to collect real-life efficacy, safety and tolerability data and to capture pregnancy outcomes. Moreover, sequencing of treatments is captured in this registry, as once a patient is in the registry, data are collected on a 6-monthly basis.

**Methods:** Neurologists who are members of the BSGMS can enter patients after approval of the BELTRIMS registry protocol by local and central ethics committees. Informed consent from each

patient is required. An electronic CRF that can be accessed from the internet, was developed, with forms for starting a treatment, patient history, laboratory tests, adverse events and serious adverse events. Six-monthly follow-up forms contain clinical status including relapses and EDSS, as well as standard MRI data. More specific data per treatment are collected optionally. The registry is governed by a steering group and owned by the BSGMS, with technical support provided by Custodix NV.

**Results:** 1408 patients have been registered by 42 centers as of May 27th, 2018. 27% of Patients are treated with fingolimod, 26% with dimethylfumarate, 24% with teriflunomide, 13% with natalizumab, 4% with alemtuzumab. 4% of patients is untreated.

**Conclusions:** We present the set-up, governance and treatment data from the BELTRIMS registry. To date, this is the first and only Belgian MS registry. The current treatment practice of MS in Belgium is reflected in this registry.

**Funding source:** this project is funded by the Belgian Charcot Foundation

This abstract has been updated and adapted from an accepted abstract for ECTRIMS 2018