

## AAN 75<sup>th</sup> ANNUAL MEETING ABSTRACT

Media Contacts:

Renee Tessman, [rtessman@aan.com](mailto:rtessman@aan.com), (612) 928-6137

Natalie Conrad, [nconrad@aan.com](mailto:nconrad@aan.com), (612) 928-6164

### EMBARGOED FOR RELEASE UNTIL 4 P.M. ET, WEDNESDAY, APRIL 19, 2023

**Abstract Title:** Teriflunomide (Aubagio) Extends The Time To Multiple Sclerosis In Radiologically Isolated Syndrome: The TERIS Study.

**Press Release Title:** Study: Drug May Delay Earliest Symptoms of Multiple Sclerosis

**Authors:** Christine Lebrun Frenay<sup>1</sup>, Aksel Siva<sup>2</sup>, Maria Pia Sormani<sup>3</sup>, Cassandre Landes-Chateau, Lydiane Mondot, Patrick Vermersch<sup>4</sup>, Caroline Papeix<sup>5</sup>, Eric Thouvenot<sup>6</sup>, Pierre Labauge, Françoise Durand-Dubief<sup>7</sup>, Husnu Efendi<sup>8</sup>, Emmanuelle Lepage<sup>9</sup>, Murat Terzi<sup>10</sup>, Nathalie Derache<sup>11</sup>, Bertrand Bourre, Robert Hoepner, Rana Karabudak<sup>12</sup>, Jerome De Seze, Jonathan Ciron<sup>13</sup>, Pierre Clavelou<sup>14</sup>, Sandrine Wiertlewski, Omer Turan, Nur Yucenar, Mikael Cohen<sup>15</sup>, Christina Azevedo<sup>16</sup>, Francesca Bovis, Orhun Kantarci, Darin Okuda<sup>17</sup>, Daniel Pelletier<sup>18</sup>

<sup>1</sup>CRCSEP Neurologie, <sup>2</sup>Istanbul University Cerrahpasa School of Medicine, <sup>3</sup>University of Genoa, <sup>4</sup>CHR de Lille, <sup>5</sup>GH Pitie Salpetriere, <sup>6</sup>CHU De Nimes - Hospital Caremeau, <sup>7</sup>CRCSEP Lyon, <sup>8</sup>Gen Pharmaceuticals, <sup>9</sup>Hospital Pontchaillou, <sup>10</sup>19 Mayis Universitesi, <sup>11</sup>Hopital Cote De Nacre, <sup>12</sup>Academic Neurologist, <sup>13</sup>CHU Toulouse, <sup>14</sup>Hopital Gabriel Montpied, <sup>15</sup>Hopital Pasteur, <sup>16</sup>University of Southern California, <sup>17</sup>UT Southwestern Medical Center, <sup>18</sup>Keck School of Medicine of USC

**Objective:** This study aims to analyze the efficacy of teriflunomide (aubagio®) in extending the time to a seminal acute or progressive demyelinating event in a cohort of radiologically isolated syndrome (RIS) subjects from Europe and Turkiye.

**Background:** RIS subjects present with MRI features typical for multiple sclerosis (MS) without clinical symptomatology suggestive of central nervous system demyelination. Earlier treatment intervention may prevent the onset of a first clinical event and reduce the risk of new lesion development on MRI, decreasing the risk of permanent neurological impairment. In 2022, the ARISE study (NCT027395420) demonstrated that treatment with dimethylfumarate resulted in >80% risk reduction in developing MS relative to placebo in RIS.

**Design/Methods:** This Phase III study (NCT03122652) enrolled 124 subjects and randomized 89 who fulfilled the 2009 RIS Criteria. Study participants were randomized 1:1 to teriflunomide (14 mg daily) or placebo. The primary outcome measure was time to the first event from study entry. All MRI and clinical data were independently adjudicated. Standardized brain and spinal cord MRI studies and clinical events were performed at baseline and weeks 48 and 96.

**Results:** Of the 89 randomized RIS subjects, 63 (70.8%) were female, mean age of 39.8 years, age at index MRI:38 y). 28 clinical events were detected during follow-up (PCB:20, teriflunomide: 8). Results from the unadjusted (HR=0.38,95% confidence interval (CI)=0.17-0.88, p=0.025) and adjusted (HR=0.34,95% CI=0.14-0.82, p=0.016) demonstrated the superiority of teriflunomide. Compared to placebo, the number of patients with Gd+ lesions (OR=0.31,95%CI:0.08-1.18, p=0.087) and the cumulative number of new or-enlarging T2 lesions (RR=0.69,95% CI=0.34-1.40, p=0.31) were reduced in the teriflunomide arm, even if the statistical significance was not achieved.

**Conclusions:** Treatment with teriflunomide resulted in a 63% risk reduction relative to placebo in preventing a first clinical event in participants with RIS. These data support early intervention with disease-modifying treatment during the presymptomatic phase of MS.

**Study Support: Sanofi**