Efficacy and safety of Nuwiq® (Human-cl rhFVIII) in clinical trials with previously treated patients with severe haemophilia A


(1) Vivantes Clinic Friedrichshain, Berlin, Germany; (2) Octapharma AG, Lachen, Switzerland; (3) Octapharma Pharmacokinetics GmbH, Vienna, Austria; (4) Great Ormond Street Hospital for Children NHS Trust, London, United Kingdom; (5) Institute of Experimental Haematology and Transfusion Medicine, University Clinic Bonn, Germany; (6) Haematology, Haemostasis, Oncology and Stem Cell Transplantation, Hannover Medical School, Hannover, Germany; (7) Georgenshoven University Medical Center, Washington DC, USA

Introduction

Nuwiq® (scophalocig alfa) is a 4th-generation recombinant factor VIII concentrate without chemical modification or fusion with any other protein. It is produced in a human cell line that adds only human-specific post-translational modifications. Nuwiq® is approved in Europe, USA, Canada, Australia, Russia and some Latin American countries for the prevention and treatment of bleeds in haemophilia A patients based on clinical trials in 135 adult and paediatric previously treated patients (PTPs) with severe haemophilia A.

Methods

- An overview of the Nuwiq® registration studies is shown in Table 1 and an overview of two recently completed studies in PTPs with severe haemophilia A, an extension study in 49 children and a pharmacokinetic-guided individualised prophylaxis study in 66 adults, is shown in Table 2.
- All studies had similar inclusion criteria and identical objective efficacy measures and safety parameters, with particular emphasis on immunogenicity.

Results

- 201 PTPs (59 children between 2 and 12 years, 142 adolescents/adults between 14 and 74 years) were enrolled in 7 prospective studies. Of these, 179 patients were treated prophylactically and 22 were treated on-demand only.
- The mean half-life of Nuwiq® (lone-stage assay) was 17.1 ± 1.11 hours in patients with severe haemophilia A (SAH). In 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTPs) with severe haemophilia A were included. To GENA-09. **
- 7 prospective clinical studies, 201 previously treated patients (PTP...