

Curriculum Vitae

Name: **BOURGEOIS Stefan, A.J.**

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Date of birth July 6, 1967

Place of birth Aalst, Belgium

Citizenship Belgian

Matrimonial status Married to Isabelle De Bruyne (orthodontic dentist)
Two children: Camille (°2004) & Thibault (°2007)

Degrees and Academical background

Primary school Sint-Jozefscollege, Kapucijnenlaan, Aalst, Belgium

High school Sint-Jozefscollege, Pontstraat, Aalst, Belgium

Medical School Catholic University of Leuven, Belgium (1985-1993)

- Doctor in Medicine, Surgery and Obstetrics (MD) with great distinction at the University of Leuven
- Residency in Internal Medicine / Gastroenterology & Hepatology (8/1993 – 7/1999 in University Hospital Gasthuisberg (Leuven) and Stuivenbergziekenhuis (Antwerp)).
- Board certification Internal Medicine in 1998
- Supervisor and staffmember at the department of Gastroenterology of the University Hospital Leuven from august 1999 till july 2000.
- Supervisor & Staffmember at the department of Internal Medicine & Gastroenterology/Hepatology at Stuivenberg hospital from august 2000 and ongoing.

- Consultant on viral hepatitis in Palfijn hospital and Middelheim hospital
- Member of the Medical Board at ZNA/STER from 2005-2008
- Member of the steering committee of BASL (Belgian Association for the study of the liver) since 2009.

Soft-ware skills:

Word, Excel, Powerpoint

Language skills:

Dutch: native language

French: excellent

English: excellent

German: basics

Scientific Work:

Experience:

- Motility lab: experiments on gastric relaxation (barostat) (promoter Prof J. Tack)
- Prospective evaluation of endoscopic ultrasound and fine-needle-aspiration of the gastro-intestinal tract (Department of endoscopy, Prof P. Rutgeerts)
- Co-investigator in ACCENT 2 study: Infliximab in Crohn-patients with fistulising disease.
- Co-investigator in several interventional en observational studies on hepatitis C treatment (Pearl, Perform, Pingu, MK 7009, Prophesys, GuardC, PegBase...)
- Principal investigator in Practice study, a non-interventional phase IV survey to assess the antiviral effectiveness of PegIntron and Rebetol treatment according to the stage of liver fibrosis in previously untreated patients with genotype 1/4/5/6 chronic hepatitis C.
- Principal investigator in Phase I, first-in-human, double-blind, randomized, placebo-controlled trial in healthy volunteers to examine the safety, tolerability, and pharmacokinetics of increasing single oral doses and of increasing repeated oral doses of TMC647055, followed by a double-blind repeated-dose part and an open-label part in chronic HCV-genotype 1 infected patients to examine the safety, tolerability and pharmacokinetics of TMC647055 given alone or in combination with TMC435.

- Principal investigator in a randomized, open-label, Phase 3 study of telaprevir administered twice daily or every 8 hours in combination with pegylated interferon alfa-2a and ribavirin in treatment-naïve subjects with genotype 1.
- Principal investigator in Phase I, first-in-human, double-blind, randomized, placebo-controlled trial in healthy volunteers to examine the safety, tolerability, and pharmacokinetics of increasing single oral doses and of increasing repeated oral doses of TMC647055, followed by a double-blind repeated-dose part and an open-label part in chronic HCV-genotype 1 infected patients to examine the safety, tolerability and pharmacokinetics of TMC647055 given alone or in combination with TMC435.
- Principal investigator in a Phase IIa, open-label trial to evaluate the safety, tolerability and efficacy of a 12 weeks combination therapy of TMC647055 and TMC435 with a pharmacokinetic enhancer with and without ribavirin in chronic genotype 1 hepatitis C infected patients
- Principal investigator in a phase III randomised, partially double-blind and placebo-controlled study of BI 207127 in combination with faldaprevir and ribavirin for chronic genotype 1 hepatitis C infection in an extended population of treatment naïve patients that includes those ineligible to receive peginterferon
- Principal investigator in a Phase 3, Safety and Efficacy Study of Boceprevir/Peginterferon Alfa-2a/ribavirin in Chronic HCV Genotype 1 IL28B CC Subjects
- Principal investigator a Multiple Dose Study to Evaluate the Safety, Pharmacokinetics and Pharmacodynamics of MK-8325 in Hepatitis C genotype 3 Infected Males
- Principal investigator in a Randomized, Open-Label Study to Evaluate the Safety and Efficacy of ABT 450/Ritonavir/ABT-267 (ABT-450/r/ABT-267) and ABT-333 Coadministered with Ribavirin (RBV) in Adults with Genotype 1 Chronic Hepatitis C Virus (HCV) Infection and Cirrhosis (TURQUOISE-II)
- Principal investigator in a phase III, randomized, double-blind, placebo-controlled study to investigate the efficacy, safety and tolerability of TMC435 versus placebo as part of a treatment regimen including peginterferon a-2a (Pegasys®) and ribavirin (Copegus®) or peginterferon cx-2b (Pegintron®) and ribavirin(Rebetol®) in treatment-naïve, genotype 1, hepatitis C-infected subjects.
- Principal investigator in a phase III, randomized, double-blind, placebo-controlled study to investigate the efficacy, safety and tolerability of TMC435 vs. placebo as part of a treatment regimen including peginterferon alfa-2a and ribavirin in hepatitis C, genotype I infected subjects who relapsed after previous interferon-based therapy.
- Principal investigator in an open-label, single-arm Phase III study to evaluate the efficacy, safety and tolerability of TMC435 in combination with PegIFN α -2a (Pegasys®) and ribavirin (Copegus®) in treatment-naïve or treatment-experienced, chronic hepatitis C virus genotype-4 infected subjects.

Certificates:

- ICH-GCP-training followed for several clinical trials (phase 1 – 2 – 3).
 - Good Clinical Practice (GCP) and Best Practices when Managing Clinical Trials (UBC, Jan 2010)
 - Investigator safety training (UBC, Nov 2009)
 - Inform for Primary Investigator performing eSignature only (v4.5) Assessment
 - ICH-GCP eLearning (May 2009)
 - Adverse Events Reporting (May 2009)
 - Informed Consent Overview (May 2009)

Abstracts:

- Poster presentation at Digestive Disease Week in San Francisco (may 1996)
 - The somatostatin-analogue octreotide inhibits tone and phasic contractile activity of the gastric fundus in man.
- Poster presentation at Digestive Disease Week in New Orleans (may 1998)
 - Prospective evaluation of endoscopic ultrasound guided fine needle aspiration for pancreatic lesions.
- Poster presentation at Digestive Disease Week in Orlando (may 1999)
 - A learning curve: endoscopic ultrasound guided fine needle aspiration of pancreatic lesions.
- Poster presentation at Digestive Disease Week in Orlando (may 1999)
 - Bacteremia after EUS guided puncture: a prospective analysis.
- Poster presentation at Digestive Disease Week in San Diego (may 2000)
 - Two & four mg/kg/dag of IV cyclosporin are equally effective in severe attacks of ulcerative colitis.
- Poster presentation at Digestive Disease Week in San Diego (may 2000)
 - Positron emission tomography (PET) compared to EUS & spiral CT in staging of patients with potentially operable esophageal carcinoma.
- Poster presentation at Digestive Disease Week in San Francisco (may 2002)
 - Prospective Evaluation of Endoscopic Ultrasound (EUS) Guided Fine Needle Aspiration (FNA) for Pancreatic Lesions: Defining a Learning Curve
- Poster presentation at European Congress of Radiology in Vienna (march 2002)
 - Intestinal Involvement in Acute Pancreatitis: CT findings
- Poster presentation at Belgian Week of Gastroenterology in Antwerp (february 2008)
 - Observation study assessing the antiviral effectiveness of PegIntron and Rebetol, according to the stage of liver fibrosis, in naïve patients with genotype 1,4,5,6 chronic hepatitis C.
- Poster presentation at EASL in Vienna (april 2010)

- High Viral Response in a Multidisciplinary Network not organized under one roof for antiviral management of chronic hepatitis C viral Patients infected after substance use.
- Poster presentation at INHSU in Brussels (September 2011)
 - Ex-IDU are good candidates for treatment in the DAA-era: results from routine clinical practice on SVR & adherence
- Poster presentation at AASLD in San Francisco (November 2011)
 - Human safety, pharmacokinetics and antiviral activity of TMC647055, a novel HCV non-nucleoside polymerase inhibitor
- Poster presentation at Belgian Week of Gastro-enterology (februari 2013)
 - Virological response in Belgian CHC patients treated with Peginterferon alfa-2/ribavirin: a sub-analysis of the final population from the prophesys study.
- Poster presentation at EASL in Amsterdam (april 2013)
 - Combination therapy of TMC647055 with simeprevir (TMC435) in chronic hepatitis C patients

Oral Presentations

- Adherence but not loss to follow-up in genotype 1 and 4 chronic hepatitis C patients infected after substance use is similar in comparison with infection by other causes: data from a large 'real life' trial. (presented at INHSU, Brussels, September 2011)
- State-of-the-Art: de wisselwerking tussen Hepatitis C en metabole factoren (presented at 'Geneeskundige dagen van Antwerpen', Edegem, September 2010)

Publications

- Trage verstikkingsdood door morbiede obesitas. S. Bourgeois et al. Tijdschrift voor Geneeskunde, 1996;52(205-7)
- Fatal Yersinia enterocolitica transfusion reaction. J. Verhaegen, S. Bourgeois et al. Journal of Clinical Pathology 1997;50(796)
- Images in Clinical Radiology : Ascaris Lumbricoides. A. De Backer, B. De Keulenaer, K. Mortelé, P. Ros, S. Bourgeois, I Vanschoubroeck. JBR-BTR, 2002, 85: 265
- Guidelines for the management of chronic hepatitis C in patients infected after substance use. Robaey G, Buntinx F, Bottieau E, Bourgeois S et al. Acta Gastroenterol Belg, 2005; 68(1):38-45
- Efficacy of the Long-Acting Repeatable Formulation of the Somatostatin Analogue Octreotide in Postoperative Dumping. Arts J, Caenepeel P, Bisschops R, Dewulf D,

Holvoet L, Piessevaux H, Bourgeois S, Sifrim D, Janssens J, Tack J. Clin Gastroenterol Hepatol. 2009; 7(4):432-7

- Reactivatie van HBsAg-negatieve hepatitis B door chemotherapie voor non-Hodgkinlymfoom: risicofactoren en preventie. S. Vellinga, S. Bourgeois, P. Zachee, K Wu. Tijdschrift voor Geneeskunde, 2009;65(952-954)
- IL28B polymorphism and the control of hepatitis C virus infection: ready for clinical use? H Orlent, H. Reynaert, S Bourgeois. Acta Gastroenterol Belg. 2011; 74(2):317-22.
- Update of the Belgian Association for the Study of the Liver guidelines for the treatment of chronic hepatitis C genotype 1 with protease inhibitors. Orlent H, Deltenre P, Francque S, Laleman W, Moreno C, Bourgeois S et al. Acta Gastroenterol Belg. 2012 ;75(2):245-59.
- Hepatitis B virus and hepatitis C virus infections in Belgium: similarities and differences in epidemics and initial management. De Vroey B, Moreno C, Laleman W, van Gossum M, Colle I, de Galocsy C, Langlet P, Robaey G, Orlent H, Michiels P, Delwaide J, Reynaert H, D'Heygere F, Sprengers D, Bourgeois S et al. Eur J Gastroenterol Hepatol. 2013 Jan 15

Distinctions

- Best oral presentation at the Belgian Week of Gastroenterology (march 1998)
- Poster of distinction at DDW 1999