BIOGRAPHICAL SKETCH

NAME: GALY, Anne

POSITION TITLE: Director of the ART-TG (Accelerator of Technological Research in Genomic Therapy), Inserm DR

EDUCATION/TRAINING:

DNAX research Institute, Palo Alto, CA USA (H Spits)	Post doctorate	1990-1992	Immunology
University C. Bernard, Lyon, France (JL Touraine)	Ph.D.	1989	Immunology
Hospices Civils de Lyon, Lyon, France	Residency	1983-1989	Medical Biology
University of South Florida, Tampa, FL, USA (J Hadden)	Undergraduate (visiting)	1987-1988	Immunopharmacology
University C. Bernard, Lyon, France (JL Touraine)	Pharm.D.	1985	Pharmacy

A. PERSONAL STATEMENT

For the past 20 years, my research has been centered around gene therapy and the immune system. At Genethon, a laboratory focused on the gene therapy of rare genetic diseases, I was able to develop hematopoietic stem cell-based gene therapies using lentiviral vectors that led to several successful international phase I/II clinical trials in primary immune deficiencies or blood disorders (e.g. Net4CGD network); a work recognized by several prizes and honors. I have also studied unwanted immune responses to gene therapy viral vectors and developed endogenized vectors expected to have low immunogenicity. More recently, I have established an Inserm laboratory, the "accelerator of technological research" in gene therapy (ART-TG) (www.art-tg.com) to explore novel genetic immunotherapies and to provide a supportive capacity for translational resarch in cell and gene therapies, serving the needs of academia and start-ups. Author of 130+ articles (i10 index 121) and inventor of several patents, my research is actively funded and connected to international networks. I am currently a member of the Vaccine Research Institute, affiliated to the Mondor Institute for Biomedical research, and I coordinate the THERA-B national program for genetically-engineering B cells. I am a board member of the European Society of Cell and Gene Therapy and chair its committee on infectious diseases and vaccines.

B. POSITIONS AND HONORS

Positions

2018-present Director of the ART-TG facility (Inserm unit US35), Corbeil-Essonnes, France
2023-present Member, Institute Mondor for Biomedical Research, U955, Créteil, France
2021-present Member of the Vaccine Research Institute (VRI) labex, Créteil, France
2013- 2023 Head of the Therapeutic Program "Blood and Immune Disorders", Genethon, Evry, France
2012-present Inserm Director of Research level 1
2009-2023 Director of the Inserm research unit UMR_S951 at Genethon, Evry, France
2001-2006 Team leader Inserm unit U362/U790, Institut Gustave Roussy Cancer Center, Villejuif, France
2001-2012 Inserm Director of Research level 2
2000-2001 Technical Director, Cell Lab, Karmanos Cancer Institute, Detroit, MI USA
1995-2001 Assistant professor, promoted in 2001 to tenured associate professor, Department of Immunology Microbiology and Department of Cancer Institute Wayne State University School of Medicine, Detroit, MI USA
1992-1995 Scientist, Experimental Cellular Therapy, SySTEMix Inc., Palo Alto, CA USA

Honors

2023 Laureate Grand prize National Academy of Pharmacy
2022 Callahan outstanding service award, Wiskott Foundation
2014 Decorated as "Chevalier de la Légion d'Honneur", a national merit recognition in France

2009 Prize “Biothérapie” ThermoFisher Scientific, France

C. CONTRIBUTIONS TO SCIENCE

Publications in the last 15 years

1. Vendomele, J., Chauveau, G.A., Dalkara, D., **Galy, A.,** and Fisson, S. (2024). Peripheral Cellular Immune Responses Induced by Subretinal AAV Gene Transfer can be Restrained by the Subretinal Associated Immune Inhibition Mechanism. **Hum Gene Ther**. 10.1089/hum.2023.191**.**

2. Das, S., Rruga, F., Montepeloso, A., Dimartino, A., Spadini, S., Corre, G., Patel, J., Cavalca, E., Ferro, F., Gatti, A., Milazzo, R., **Galy, A**., Politi, L.S., Rizzardi, G.P., Vallanti, G., Poletti, V., and Biffi, A. (2024). An empowered, clinically viable hematopoietic stem cell gene therapy for the treatment of multisystemic mucopolysaccharidosis type II. **Mol Ther** 32, 619-636. 10.1016/j.ymthe.2024.01.034

3. **Galy, A**., and Dewannieux, M. (2023). Recent advances in hematopoietic gene therapy for genetic disorders. **Arch Pediatr** *30*, 8S24-28S31. 10.1016/S0929-693X(23)00224-5.

4. **Galy, A.**, B. Berkhout, K. Breckpot, C. Pichon, K. Bloom, H. P. Kiem, M. D. Muhlebach and J. M. McCune (2023). "Recent advances using genetic therapies against infectious diseases and for vaccination." **Hum Gene Ther**. 2023 Sep;34(17-18):896-904. doi: 10.1089/hum.2023.123

5. Labrosse, R., J. Chu, M. Armant, J. K. Everett, D. Pellin, N. Kareddy, A. L. Frelinger, L. A. Henderson, A. E. O'Connell, A. Biswas, J. Coenen-van der Spek, A. M. Miggelbrink, C. Fiorini, H. Adhikari, C. C. Berry, V. A. Cantu, J. Fong, J. R. Jaroslavsky, D. F. Karadeniz, Q. Z. Li, S. Reddy, A. M. Roche, C. Zhu, J. S. Whangbo, C. Dansereau, B. L. Mackinnon, E. Morris, S. M. Koo, W. B. London, S. Baris, A. Ozen, E. Karakoc-Aydiner, J. M. Despotovic, L. R. Forbes Satter, A. Saitoh, Y. Aizawa, A. King, M. A. T. Nguyen, V. D. U. Vu, S. B. Snapper, **A. Galy**, L. D. Notarangelo, F. D. Bushman, D. A. Williams and S. Y. Pai (2023). "Outcomes of Hematopoietic Stem Cell Gene Therapy for Wiskott-Aldrich Syndrome." **Blood**. 2023 Oct 12;142(15):1281-1296. doi: 10.1182/blood.2022019117.

6. Corre, G. and **A. Galy** (2023). "Evaluation of diversity indices to estimate clonal dominance in gene therapy studies." **Mol Ther Methods Clin Dev** 29: 418-425.

7. Sobrino, S., A. Magnani, M. Semeraro, L. Martignetti, A. Cortal, A. Denis, C. Couzin, C. Picard, J. Bustamante, E. Magrin, L. Joseph, C. Roudaut, A. Gabrion, T. Soheili, C. Cordier, O. Lortholary, F. Lefrere, F. Rieux-Laucat, J. L. Casanova, S. Bodard, N. Boddaert, A. J. Thrasher, F. Touzot, S. Taque, F. Suarez, A. Marcais, A. Guilloux, C. Lagresle-Peyrou, **A. Galy**, A. Rausell, S. Blanche, M. Cavazzana, and E. Six. 2023. 'Severe hematopoietic stem cell inflammation compromises chronic granulomatous disease gene therapy'**, Cell Rep Med**: 100919.

8. Ueda, N., Cahen, M., Sirac, C., **Galy, A**., Moreaux, J. Danger, Y. Cogné, M.. 2022 Single-hit genome edition for expression of single-chain immunoglobulins by edited B cells. **bioRxiv** 2022.06.02.494471; doi: https://doi.org/10.1101/2022.06.02.494471

9. Buffa, V., J. R. Alvarez Vargas, **A. Galy**, S. Spinozzi, and C. J. Rocca. 2022. 'Hematopoietic stem and progenitors cells gene editing: Beyond blood disorders', **Front Genome Ed**, 4: 997142.

10. Magnani, A, Semeraro, M, Adam, F, Booth, C, Dupre, L, Morris, EC, Gabrion, A, Roudaut, C, Borgel, D, Toubert, A, Clave, E, Abdo, C, Gorochov, G, Petermann, R, Guiot, M, Miyara, M, Moshous, D, Magrin, E, Denis, A, Suarez, F, Lagresle, C, Roche, AM, Everett, J, Trinquand, A, Guisset, M, Bayford, JX, Hacein-Bey-Abina, S, Kauskot, A, Elfeky, R, Rivat, C, Abbas, S, Gaspar, HB, Macintyre, E, Picard, C, Bushman, FD, **Galy, A**, Fischer, A, Six, E, Thrasher, AJ, and Cavazzana, M (2022). Long-term safety and efficacy of lentiviral hematopoietic stem/progenitor cell gene therapy for Wiskott-Aldrich syndrome. **Nat Med** 28: 71-80.

11. Donnadieu, E, Luu, M, Alb, M, Anliker, B, Arcangeli, S, Bonini, C, De Angelis, B, Choudhary, R, Espie, D, **Galy, A**, Holland, C, Ivics, Z, Kantari-Mimoun, C, Kersten, MJ, Kohl, U, Kuhn, C, Laugel, B, Locatelli, F, Marchiq, I, Markman, J, Moresco, MA, Morris, E, Negre, H, Quintarelli, C, Rade, M, Reiche, K, Renner, M, Ruggiero, E, Sanges, C, Stauss, H, Themeli, M, Van den Brulle, J, Hudecek, M, and Casucci, M (2022). Time to evolve: predicting engineered T cell-associated toxicity with next-generation models. **J Immunother Cancer** 10.

12. Corre, G, Seye, A, Frin, S, Ferrand, M, Winkler, K, Luc, C, Dorange, F, Rocca, CJ, and **Galy, A** (2022). Lentiviral standards to determine the sensitivity of assays that quantify lentiviral vector copy numbers and genomic insertion sites in cells. **Gene Ther**. doi: 10.1038/s41434-022-00315-8

13. Six, E, Guilloux, A, Denis, A, Lecoules, A, Magnani, A, Vilette, R, Male, F, Cagnard, N, Delville, M, Magrin, E, Caccavelli, L, Roudaut, C, Plantier, C, Sobrino, S, Gregg, J, Nobles, CL, Everett, JK, Hacein-Bey-Abina, S, **Galy, A**, Fischer, A, Thrasher, AJ, Andre, I, Cavazzana, M, and Bushman, FD (2020). Clonal tracking in gene therapy patients reveals a diversity of human hematopoietic differentiation programs. **Blood** 135: 1219-1231.

14. Munoz, P, Tristan-Manzano, M, Sanchez-Gilabert, A, Santilli, G, **Galy, A**, Thrasher, AJ, and Martin, F (2020). WAS Promoter-Driven Lentiviral Vectors Mimic Closely the Lopsided WASP Expression during Megakaryocytic Differentiation. **Mol Ther Methods Clin Dev** 19: 220-235.

15. Kohn, DB, Booth, C, Kang, EM, Pai, SY, Shaw, KL, Santilli, G, Armant, M, Buckland, KF, Choi, U, De Ravin, SS, Dorsey, MJ, Kuo, CY, Leon-Rico, D, Rivat, C, Izotova, N, Gilmour, K, Snell, K, Dip, JX, Darwish, J, Morris, EC, Terrazas, D, Wang, LD, Bauser, CA, Paprotka, T, Kuhns, DB, Gregg, J, Raymond, HE, Everett, JK, Honnet, G, Biasco, L, Newburger, PE, Bushman, FD, Grez, M, Gaspar, HB, Williams, DA, Malech, HL, **Galy, A**, Thrasher, AJ, and Net4CGD (2020). Lentiviral gene therapy for X-linked chronic granulomatous disease. **Nat Med** 26: 200-206.

16. Coquin, Y, Ferrand, M, Seye, A, Menu, L, and **Galy, A** (2020). Syncytins enable novel possibilities to transduce human or mouse primary B cells and to achieve well-tolerated in vivo gene transfer. **bioRxiv** 816223; doi: https://doiorg/101101/816223.

17. Rio, P, Navarro, S, Wang, W, Sanchez-Dominguez, R, Pujol, RM, Segovia, JC, Bogliolo, M, Merino, E, Wu, N, Salgado, R, Lamana, ML, Yanez, RM, Casado, JA, Gimenez, Y, Roman-Rodriguez, FJ, Alvarez, L, Alberquilla, O, Raimbault, A, Guenechea, G, Lozano, ML, Cerrato, L, Hernando, M, Galvez, E, Hladun, R, Giralt, I, Barquinero, J, **Galy, A**, Garcia de Andoin, N, Lopez, R, Catala, A, Schwartz, JD, Surralles, J, Soulier, J, Schmidt, M, Diaz de Heredia, C, Sevilla, J, and Bueren, JA (2019). Successful engraftment of gene-corrected hematopoietic stem cells in non-conditioned patients with Fanconi anemia. **Nat Med** 25: 1396-1401.

18. Radek, C, Bernadin, O, Drechsel, K, Cordes, N, Pfeifer, R, Strasser, P, Mormin, M, Gutierrez-Guerrero, A, Cosset, FL, Kaiser, AD, Schaser, T, **Galy, A**, Verhoeyen, E, and Johnston, ICD (2019). Vectofusin-1 Improves Transduction of Primary Human Cells with Diverse Retroviral and Lentiviral Pseudotypes, Enabling Robust, Automated Closed-System Manufacturing. **Hum Gene Ther** 30: 1477-1493.

19. Da Rocha, S, Bigot, J, Onodi, F, Cosette, J, Corre, G, Poupiot, J, Fenard, D, Gjata, B, **Galy, A**, and Neildez-Nguyen, TMA (2019). Temporary Reduction of Membrane CD4 with the Antioxidant MnTBAP Is Sufficient to Prevent Immune Responses Induced by Gene Transfer. **Mol Ther Methods Clin Dev** 14: 285-299.

20. Charrier, S, Lagresle-Peyrou, C, Poletti, V, Rothe, M, Cedrone, G, Gjata, B, Mavilio, F, Fischer, A, Schambach, A, de Villartay, JP, Cavazzana, M, Hacein-Bey-Abina, S, and **Galy, A** (2019). Biosafety Studies of a Clinically Applicable Lentiviral Vector for the Gene Therapy of Artemis-SCID. **Mol Ther Methods Clin Dev** 15: 232-245.

21. Boudeffa, D, Bertin, B, Biek, A, Mormin, M, Leseigneur, F, **Galy, A***, and Merten, OW (2019). Toward a Scalable Purification Protocol of GaLV-TR-Pseudotyped Lentiviral Vectors. **Hum Gene Ther Methods** 30: 153-171.*co-corresponding

22. Vendomele, J, Dehmani, S, Khebizi, Q, **Galy, A**, and Fisson, S (2018). Subretinal Injection of HY Peptides Induces Systemic Antigen-Specific Inhibition of Effector CD4(+) and CD8(+) T-Cell responses. **Frontiers in Immunology** Mar 13;9:504. doi: 10.3389/fimmu.2018.00504. eCollection 2018.

23. Brendel, C, Rothe, M, Santilli, G, Charrier, S, Stein, S, Kunkel, H, Abriss, D, Muller-Kuller, U, Gaspar, B, Modlich, U, **Galy, A**, Schambach, A, Thrasher, AJ, and Grez, M (2018). Non-Clinical Efficacy and Safety Studies on G1XCGD, a Lentiviral Vector for Ex Vivo Gene Therapy of X-Linked Chronic Granulomatous Disease. **Hum Gene Ther Clin Dev** 29: 69-79.

24. Vermeer, LS, Hamon, L, Schirer, A, Schoup, M, Cosette, J, Majdoul, S, Pastre, D, Stockholm, D, Holic, N, Hellwig, P, **Galy, A**, Fenard, D, and Bechinger, B (2017). Vectofusin-1, a potent peptidic enhancer of viral gene transfer forms pH-dependent alpha-helical nanofibrils, concentrating viral particles. **Acta Biomater** 64: 259-268.

25. Rio, P, Navarro, S, Guenechea, G, Sanchez-Dominguez, R, Lamana, ML, Yanez, R, Casado, JA, Mehta, PA, Pujol, MR, Surralles, J, Charrier, S, **Galy, A**, Segovia, JC, Diaz de Heredia, C, Sevilla, J, and Bueren, JA (2017). Engraftment and in vivo proliferation advantage of gene-corrected mobilized CD34(+) cells from Fanconi anemia patients. **Blood** 130: 1535-1542.

26. Piovan, C, Marin, V, Scavullo, C, Corna, S, Giuliani, E, Bossi, S, **Galy, A**, Fenard, D, Bordignon, C, Rizzardi, GP, and Bovolenta, C (2017). Vectofusin-1 Promotes RD114-TR-Pseudotyped Lentiviral Vector Transduction of Human HSPCs and T Lymphocytes. **Mol Ther Methods Clin Dev** 5: 22-30.

27. Morris, EC, Fox, T, Chakraverty, R, Tendeiro, R, Snell, K, Rivat, C, Grace, S, Gilmour, K, Workman, S, Buckland, K, Butler, K, Chee, R, Salama, AD, Ibrahim, H, Hara, H, Duret, C, Mavilio, F, Male, F, Bushman, FD, **Galy, A**, Burns, SO, Gaspar, HB, and Thrasher, AJ (2017). Gene therapy for Wiskott-Aldrich syndrome in a severely affected adult. **Blood** 130: 1327-1335.

28. Majdoul, S, Cosette, J, Seye, AK, Bernard, E, Frin, S, Holic, N, Chazal, N, Briant, L, Espert, L, **Galy, A***, and Fenard, D (2017). Peptides derived from evolutionarily conserved domains in Beclin-1 and Beclin-2 enhance the entry of lentiviral vectors into human cells. **J Biol Chem** 292: 18672-18681.* co-corresponding

29. Holic, N, Frin, S, Seye, AK, **Galy, A**, and Fenard, D (2017). Improvement of De Novo Cholesterol Biosynthesis Efficiently Promotes the Production of Human Immunodeficiency Virus Type 1-Derived Lentiviral Vectors. **Hum Gene Ther Methods** 28: 67-77.

30. **Galy, A** (2017). Major Advances in the Development of Vectors for Clinical Gene Therapy of Hematopoietic Stem Cells from European Groups over the Last 25 Years. **Hum Gene Ther** 28: 964-971.

31. Vermeer, LS, Marquette, A, Schoup, M, Fenard, D, **Galy, A**, and Bechinger, B (2016). Simultaneous Analysis of Secondary Structure and Light Scattering from Circular Dichroism Titrations: Application to Vectofusin-1. **Sci Rep** 6: 39450.

32. Verhoeyen, E, Gomez, S, **Galy, A**, Ayuso, E, Midoux, P, Puceat, M, Vassaux, G, and Cordelier, P (2016). Twelfth Annual Meeting of the French Society of Cell and Gene Therapy. **Hum Gene Ther** 27: 555-558.

33. Rivera-Munoz, P, Abramowski, V, Jacquot, S, Andre, P, Charrier, S, Lipson-Ruffert, K, Fischer, A, **Galy, A**, Cavazzana, M, and de Villartay, JP (2016). Lymphopoiesis in transgenic mice over-expressing Artemis. **Gene Ther** 23: 176-186.

34. Majdoul, S, Seye, AK, Kichler, A, Holic, N, **Galy, A**, Bechinger, B, and Fenard, D (2016). Molecular Determinants of Vectofusin-1 and Its Derivatives for the Enhancement of Lentivirally Mediated Gene Transfer into Hematopoietic Stem/Progenitor Cells. **J Biol Chem** 291: 2161-2169.

35. Gregoire, S, Terrada, C, Martin, GH, Fourcade, G, Baeyens, A, Marodon, G, Fisson, S, Billiard, F, Lucas, B, Tadayoni, R, Behar-Cohen, F, Levacher, B, **Galy, A**, LeHoang, P, Klatzmann, D, Bodaghi, B, and Salomon, BL (2016). Treatment of Uveitis by In Situ Administration of Ex Vivo-Activated Polyclonal Regulatory T Cells. **J Immunol** 196: 2109-2118.

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37. Corre, G, Dessainte, M, Marteau, JB, Dalle, B, Fenard, D, and **Galy, A** (2016). "RCL-Pooling Assay": A Simplified Method for the Detection of Replication-Competent Lentiviruses in Vector Batches Using Sequential Pooling. **Hum Gene Ther** 27: 202-210.

38. Cire, S, Da Rocha, S, Ferrand, M, Collins, MK, and **Galy, A** (2016). In Vivo Gene Delivery to Lymph Node Stromal Cells Leads to Transgene-specific CD8+ T Cell Anergy in Mice. **Mol Ther** 24: 1965-1973.

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Lefrere, F, Magalon, J, Pengue-Koyi, I, Honnet, G, Blanche, S, Sherman, EA, Male, F, Berry, C, Malani, N, Bushman, FD, Fischer, A, Thrasher, AJ, **Galy, A***, and Cavazzana, M (2015). Outcomes following gene therapy in patients with severe Wiskott-Aldrich syndrome. **JAMA** 313: 1550-1563.*co-senior

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MG, and Naldini, L (2013). Lentiviral hematopoietic stem cell gene therapy in patients with Wiskott-Aldrich syndrome. **Science** 341: 1233151.

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Service activities (extracts)

2022-present Member of the board of ESGCT. Chair of Vaccine & infectious Diseases committee
2022-present Member of the executive committee of the DIM BioConvS network Ile de France Region
2019- 2024 Member of the scientific counsel of the IBISA infrastructure for scientific platforms
2020-2023 Member of the scientific counsel of the faculty of medicine of the university Paris-Saclay
2018-2023 Member of the International committee of ASGCT
2009-present Editorial member of several journals (HGT, Frontiers in Medicine, Gene Therapy)
2018 Missioned by the French Ministry of Research as co-lead for the Research axis of the French "Plan National Maladies Rares III"
2014-2015 Member of the scientific counsel of the LOEWE Center for Cell and Gene Therapy, Frankfurt
2011-2015 Member of the scientific evaluation committee of E-Rare
2011-2016 Member of the scientific counsel of the DIM Biotherapy – Région Ile-de-France
2012-2016 President of the scientific study section CSS8 of Inserm

Patents (recent)

PCT/EP2023/077925 A. Galy, I. Richard, M. Ferrand, C. Rocca, S. Albini « IMMUNOTHERAPY OF SKELETAL MYOPATHIES USING ANTI-FAP CAR-T CELLS » Publication 09 October 2023

PCT/EP2018/078809 A. Galy, M. Ferrand, Y. Coquin inventors, *«* USE OF SYNCYTIN FOR TARGETING DRUG AND GENE DELIVERY TO LUNG TISSUE*» Publication date* 25.04.2019

PCT/EP2017/059465. A. Galy inventor *« STABLE PSEUDOTYPED LENTIVIRAL PARTICLES AND USES THEREOF » Publication date* 26.10.2017. Delivered Japon (n° 7078547), South Korea (n°10-2445700)