Stanford

Randall Morris

Professor (Research) of Cardiothoracic Surgery, Emeritus

Resume available Online

Bio

BIO

Dr. Morris, with his teams and collaborators, discovered, patented, &/or first published on the anti-rejection or anti-restenosis activities of 4 first-in-class natural product, synthetic organic or monoclonal antibody drugs.

All branded and generic drugs within these 4 classes of therapeutics have generated aggregated annual peak sales of over approximately $10 billion and cumulative sales to date of approximately $80 billion for on- and off-label uses.

1. Sirolimus:. Dr. Morris first published that sirolimus prevents acute transplant (Tx) rejection (independently discovered at the University of Cambridge, UK) & discovered its suppression of chronic Tx rejection; Dr. Morris's lab discovered and patented the use of sirolimus/ mTOR inhibitors for the prevention of restenosis post-arterial angioplasty.

2. Mycophenolate mofetil (MMF, the pro-drug for mycophenolic acid [MPA]): Dr. Morris discovered that MMF prevents and treats acute Tx rejection; MMF and MPA became & remain the most prescribed immunosuppressants for recipients of all types of transplanted organ, cell and bone marrow transplants.

3. Tofacitinib: Dr. Morris's lab, in collaboration with scientists from Pfizer, first published that tofacitinib prevents acute Tx rejection.

4. Efalizumab: Dr. Morris, in collaboration with scientists from Genentech, first published efalizumab prevents acute Tx rejection.

These classes of drugs were subsequently further developed in the clinic by several pharmaceutical companies, with Dr. Morris often as an advisor, and received world-wide regulatory marketing approvals for a total of 7 indications:

1. Suppression of acute renal transplant rejection and/or,

2. Prevention of acute liver transplant rejection and/or.

3. Prevention of acute heart transplant rejection and/or,

4. Prevention of chronic (coronary artery vasculopathy) heart transplant rejection and/or,

5. Prevention of coronary artery restenosis after angioplasty (Dr. Morris is the co-inventor on the foundational patent for mTOR inhibitor drug - eluting stents), or

6. Treatment of rheumatoid arthritis or,

7. Treatment of psoriasis.

At Novartis, Dr. Morris oversaw the preclinical discovery and early clinical development of the first-in-class selective protein kinase C inhibitor immunosuppressant, sotrastaurin (AEB071), which advanced through four Ph 2 trials in renal transplant patients.

ACADEMIC APPOINTMENTS

- Emeritus Faculty, Acad Council, Cardiothoracic Surgery

LINKS

- My website: http://www.randallemorris.com

Research & Scholarship

CURRENT RESEARCH AND SCHOLARLY INTERESTS

R&D (pre-clinical discovery and clinical trial development) for novel therapeutics for prevention and treatment of immune, inflammatory, ischemic and other causes for injuries to all types of organ and cell allo- and xenografts and for prevention and treatment of acute organ injury/dysfunction/failure, acute graft-vs. -host disease after hematopoietic stem cell transplantation, and prevention and treatment of autoimmune diseases, the relationships between drug pharmacokinetics and pharmacodynamics, the discovery and clinical development of novel therapeutic technologies designed to selectively target small molecule immunosuppressants to specific immune cell subsets and tissues, the use of new technologies for measuring biomarkers and biomarker measures for surrogate endpoints for accelerated regulatory drug marketing approvals and novel clinical trial designs.

Publications

PUBLICATIONS

- **The Importance of Drug Safety and Tolerability in the Development of New Immunosuppressive Therapy for Transplant Recipients.** *American journal of transplantation : official journal of the American Society of Transplantation and the American Society of Transplant Surgeons*
  Stegall, M. D., Somerville, K. T., Everly, M., Mannon, R. B., Gaber, O. A., First, M. R., Agashivala, N., Perez, V., Newell, K. A., Morris, R. E., Sudan, D., Romero, K., Eremenco, et al
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- **Therapeutic Drug Monitoring of Everolimus: A Consensus Report** *THERAPEUTIC DRUG MONITORING*
  Shipkova, M., Hesselink, D. A., Holt, D. W., Billaud, E. M., van Gelder, T., Kunicki, P. K., Brunet, M., Budde, K., Barten, M. J., De Simone, P., Wieland, E., Millan Lopez, O., Masuda, et al
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- **Advances in Transplantation: Editorial.** *Clinical transplants*
  Morris, R. E.
  2015; 31: 147-150

- **The xenoantibody response and immunoglobulin gene expression profile of cynomolgus monkeys transplanted with hDAF-transgenic porcine hearts** *XENOTRANSPLANTATION*
  Zahorsky-Reeves, J. L., Kearns-Jonker, M. K., Lam, T. T., Jackson, J. R., Morris, R. E., Starnes, V. A., Cramer, D. V.
  2007; 14 (2): 135-144

- **Immunosuppressive effects of surgery assessed by flow cytometry in nonhuman primates after nephrectomy** *TRANSPLANT INTERNATIONAL*
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- **The novel calcineurin inhibitor ISA247: a more potent immunosuppressant than cyclosporine in vitro.** *Transplant international*
  Bîrsan, T., Dambrin, C., Freitag, D. G., Yatscoff, R. W., Morris, R. E.
  2005; 17 (12): 767-771

- **Use of echocardiography to assess function of HDAF-transgenic pig cardiac xenografts** *3rd International Congress on Immunosuppression*
  Chan, M. C., Stalder, M., Lam, T. T., Tye, T., Borie, D. C., Morris, R. E.
  ELSEVIER SCIENCE INC.2005: 1923–25

- **Immunosuppression by the JAK3 inhibitor CP-690,550 delays rejection and significantly prolongs kidney allograft survival in nonhuman primates** *TRANSPLANTATION*
  Borie, D. C., Changelian, P. S., Larson, M. J., Si, M. S., Paniagua, R., Higgins, J. P., Holm, B., Campbell, A., Lau, M., Zhang, S., Flores, M. G., Rousvoal, G., Hawkins, et al
  2005; 79 (7): 791-801

- **Improved assessment of graft function by echocardiography in cynomolgus monkey recipients of hDAF-transgenic pig cardiac xenografts** *JOURNAL OF HEART AND LUNG TRANSPLANTATION*
  Stalder, M., Tye, T., Lam, T. T., Chan, M. C., Berry, G. J., Borie, D. C., Morris, R. E.
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- **The effect of soluble complement receptor type 1 on acute humoral xenograft rejection in hDAF-transgenic pig-to-primate life-supporting kidney xenografts** *XENOTRANSPLANTATION*
  Lam, T. T., Hausen, B., Hook, L., Lau, M., Higgins, J., Christians, U., Jacobsen, W., Baluom, M., Duthaler, R., Katopodis, A., Chavez, G., Cozzi, E., Harrison, et al
  2005; 12 (1): 20-29

- **The novel calcineurin inhibitor ISA247: a more potent immunosuppressant than cyclosporine in vitro** *TRANSPLANT INTERNATIONAL*
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- **Hyperacute rejection of hDAF-transgenic pig organ xenografts in cynomolgus monkeys: influence of pre-existing anti-pig antibodies and prevention by the alpha GAL glycoconjugate GAS914** *XENOTRANSPLANTATION*
  Lam, T. T., Hausen, B., Boeke-Purkis, K., Paniagua, R., Lau, M., Hook, L., Berry, G., Higgins, J., Duthaler, R. O., Katopodis, A. G., Robbins, R., Reitz, B., Borie, et al
  2004; 11 (6): 517-524

- **Anti-non-Gal porcine endothelial cell antibodies in acute humoral xenograft rejection of hDAF-transgenic porcine hearts in cynomolgus monkeys** *XENOTRANSPLANTATION*
  Lam, T. T., Paniagua, R., Shivaram, G., Schuurman, H. J., Borie, D. C., Morris, R. E.
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- **Compared with cyclosporine, ISA(TX)247 significantly prolongs renal-allograft survival in a nonhuman primate model** *TRANSPLANTATION*
  Gregory, C. R., Kyles, A. E., Bernsteen, L., Wagner, G. S., TARANTAL, A. F., Christe, K. L., Brignolo, L., Spinner, A., Griffey, S. M., Paniagua, R. T., Hubble, R. W., Borie, D. C., Morris, et al
  2004; 78 (5): 681-685

- **Anti-pig antibody levels in non-human primates of various origin** *XENOTRANSPLANTATION*
  Lam, T. T., Boeke-Purkis, K., Lau, M., Paniagua, R., Schuurman, H. J., Morris, R. E.
  2004; 11 (4): 332-339

- **In vitro evaluation of the effects of candidate immuno suppressive drugs: flow cytometry and quantitative real-time PCR as two independent and correlated read-outs** *JOURNAL OF IMMUNOLOGICAL METHODS*
  Flores, M. G., Zhang, S., Ha, A., Holm, B., Reitz, B. A., Morris, R. E., Borie, D. C.
  2004; 289 (1-2): 123-135

- **Effects of AGI-1096, a novel antioxidant compound with anti-inflammatory and antiproliferative properties, on rodent allograft arteriosclerosis** *TRANSPLANTATION*
  Murata, S., Sundell, C. L., Lijkwan, M. A., Balsam, L. B., Hammainen, P., Coleman, C., York, C., Luchoomun, J., Suen, K. L., Howard, R., Somers, P. K., Morris, R. E., Robbins, et al

2004; 77 (10): 1494-1500

- **Respiratory epithelial expression of integrin alpha V beta(6) in chronic progressive allograft rejection** *JOURNAL OF HEART AND LUNG TRANSPLANTATION*
  Dosanjh, A., Ikonen, T., Morris, R.
  2004; 23 (4): 456-460

- **Preliminary in vivo pharmacokinetic and pharmacodynamic evaluation of a novel calcineurin-independent inhibitor of NFAT** *TRANSPLANT INTERNATIONAL*
  Birsan, T., Dambrin, C., Marsh, K. C., Jacobsen, W., Djuric, S. W., Mollison, K. W., Christians, U., Carter, G. W., Morris, R. E.
  2004; 17 (3): 145-150

- **Sustained suppression of peripheral blood immune functions by treatment with mycophenolate mofetil correlates with reduced severity of cardiac allograft rejection** *JOURNAL OF HEART AND LUNG TRANSPLANTATION*
  Klupp, J., van Gelder, T., Dambrin, C., Regieli, J. J., Boeke, K., Billingham, M. E., Morris, R. E.
  2004; 23 (3): 334-351

- **Histological and immunological characteristics of, and the effect of immunosuppressive treatment on, xenograft vasculopathy** *XENOTRANSPLANTATION*
  Briffa, N. P., Shorthouse, R., Chan, J., Silva, H., Billingham, M., Brazelton, T., Morris, R. E.
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- **In vivo evaluation of the novel calcineurin inhibitor ISA(Tx)247 in non-human primates** *JOURNAL OF HEART AND LUNG TRANSPLANTATION*
  Stalder, M., Birsan, T., Hubble, R. W., Paniagua, R. T., Morris, R. E.
  2003; 22 (12): 1343-1352

- **JAK3 inhibition as a new concept for immune suppression.** *Current opinion in investigational drugs*
  Borie, D. C., Si, M., Morris, R. E., Reitz, B. A., Changelian, P. S.
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- **Treatment by mycophenolate mofetil of advanced graft vascular disease in non-human primate recipients of orthotopic aortic allografts** *AMERICAN JOURNAL OF TRANSPLANTATION*
  Klupp, J., Dambrin, C., Hibi, K., Luna, J., Suzuki, T., Hausen, B., Birsan, T., van Gelder, T., Fitzgerald, P. J., Berry, G., Morris, R. E.
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  Birsan, T., Hausen, B., Higgins, J. P., Hubble, R. W., Klupp, J., Stalder, M., Celniker, A., Friedrich, S., O'Hara, R. M., Morris, R. E.
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- **Sirolimus (rapamycin) monotherapy prevents graft vascular disease in nonhuman primate recipients of orthotopic aortic allografts** *CIRCULATION*
  Dambrin, C., Klupp, J., Birsan, T., Luna, J., Suzuki, T., Lam, T., Stahr, P., Hausen, B., Christians, U., Fitzgerald, P., Berry, G., Morris, R.
  2003; 107 (18): 2369-2374

- **In vivo pharmacokinetic and pharmacodynamic evaluation of the malononitrilamide FK778 in non-human primates** *TRANSPLANT INTERNATIONAL*
  Birsan, T., Dambrin, C., Klupp, J., Stalder, M., Larson, M. J., Fitzsimmons, W. E., Morris, R. E.
  2003; 16 (5): 354-360

- **Immunosuppression with a combination of the leflunomide analog, FK778, and microemulsified cyclosporine for renal transplantation in mongrel dogs** *19th International Congress of the Transplantation-Society*
  Kyles, A. E., Gregory, C. R., Griffey, S. M., Bernsteen, L., Pierce, J., Lilja, H. S., Morris, R. E.
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- **Effects of the malononitrilamide FK778 on immune functions in vitro in whole blood from non-human primates and healthy human volunteers** *TRANSPLANT IMMUNOLOGY*
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  2003; 11 (2): 163-167
- **Graft thrombosis in hDAF-transgenic pig hearts transplanted into rhesus monkeys** *XENOTRANSPLANTATION*
  Lam, T. T., Borie, D., Masek, M., Berry, G., Larson, M., Morris, R. E.
  2003; 10 (2): 185-186
- **Quantification of immunosuppression by flow cytometry in stable renal transplant recipients** *THERAPEUTIC DRUG MONITORING*
  Stalder, M., Birsan, T., Holm, B., Haririfar, M., Scandling, J., Morris, R. E.
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- **Pharmacodynamics of mycophenolate mofetil after heart transplantation: New mechanisms of action and correlations with histologic severity of graft rejection** *AMERICAN JOURNAL OF TRANSPLANTATION*
  Barten, M. J., van Gelder, T., Gummert, J. F., Boeke, K., Shorthouse, R., Billingham, M. E., Morris, R. E.
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- **Cyclophosphamide-induced postoperative anemia in cynomolgus monkey recipients of hDAF-transgenic pig organ xenografts** *2nd International Congress on Immunosuppression*
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- **An evaluation of combined immunosuppression with MNA 715 and microemulsified cyclosporine on renal allograft rejection in mismatched mongrel dogs** *35th Annual Meeting of the American-College-of-Veterinary-Surgeons*
  Kyles, A. E., Gregory, C. R., Griffey, S. M., Jackson, J., Bernsteen, L., Morris, R. E.
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- **Novel assays of multiple lymphocyte functions in whole blood measure - New mechanisms of action of mycophenolate mofetil in vivo** *TRANSPLANT IMMUNOLOGY*
  Barten, M. J., van Gelder, T., Gummert, J. F., Shorthouse, R., Morris, R. E.
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  2002; 15 (5): 433-437
- **Evaluation of the clinical and histologic features of renal allograft rejection in cats** *VETERINARY SURGERY*
  Kyles, A. E., Gregory, C. R., Griffey, S. M., Galvez, J., Ramsamooj, R., Morris, R. E.
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- **Airway goblet cells and respiratory epithelial injury in an animal model of obliterative airways disease (OAD)** *AMERICAN JOURNAL OF TRANSPLANTATION*
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- **Hamster cardiac xenografts are protected against antibody mediated damage, early after transplantation to Lewis rats** *XENOTRANSPLANTATION*
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- **Coadministration of either cyclosporine or steroids with humanized monoclonal antibodies against CD80 and CD86 successfully prolong allograft survival after life supporting renal transplantation in cynomolgus monkeys** *TRANSPLANTATION*
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- **Viral serine proteinase inhibitor (SERP-1) effectively decreases the incidence of graft vasculopathy in heterotopic heart allografts** *TRANSPLANTATION*
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  Morris, R. E.
  LIPPINCOTT WILLIAMS & WILKINS.2001: SS37–SS41

- **Prolonged inhibition of obliterative airway disease in murine tracheal allografts by brief treatment with anti-leukocyte function-associated antigen-1 (CD11a) monoclonal antibody** *16th Annual Meeting of the American-Society-of-Transplant-Physicians*
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  van Gelder, T., Klupp, J., Sawamoto, T., Christians, U., Morris, R. E.
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  Klupp, J., van Gelder, T., Dambrin, C., Regieli, J., Boeke, K., Billingham, M. E., Morris, R. E.
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  Barten, M. J., van Gelder, T., Gummert, J. F., Shorthouse, R., Boeke, K., Billingham, M. E., Morris, R. E.
  ELSEVIER SCIENCE INC.2001: 2254–55

- **Assessment of mechanisms of action of immunosuppressive drugs using novel whole blood assays** *4th International Conference on New Trends in Clinical and Experimental Immunosuppression*
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